Table of Contents

Introduction

The Medical Treatment Guidelines review criteria contained herein were developed by the Washington State Medical Association Industrial Insurance Advisory Committee in collaboration with the Office of the Medical Director. These guidelines/review criteria are published by the Department of Labor and Industries as educational tools for providers.

In addition, the guidelines/review criteria are implemented in prospective utilization management programs, the responsibility for which is solely that of the Department of Labor and Industries.

Note: *For more copies of the Medical Treatment Guidelines please write to: L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.*

Review, Regulate, or Reform?

WHAT WORKS TO CONTROL WORKERS' COMPENSATION MEDICAL COSTS

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WORKERS COMPENSATION RESEARCH INSTITUTE
Published in 1994

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Medical Practice Guidelines in Washington Workers' Compensation

Background

The Washington State Medical Association (WSMA) Industrial Insurance Advisory Committee, in conjunction with the Washington State Department of Labor and Industries (L&I), has developed a process for establishing medical practice guidelines. Under authority of WAC 296-20-01001, the WSMA committee advises and assists L&I on issues broadly related to the quality of medical care received by injured workers. Since September 1988, two working subcommittees of the WSMA committee have met on a monthly basis to address 1) medical practice guidelines and 2) issues related to work disability among injured workers. These two subcommittees were established simultaneously because, in the view of WSMA members, injured workers receiving surgery were less likely to recover if disability-related issues were prominent at the time of surgery. Because of the complexity of the disability issue, the work of these two subcommittees has been difficult to merge. Nonetheless, the most recent guidelines (e.g. lumbar fusion) have incorporated disability related issues.

The need to establish practice guidelines was recognized by the members of the Washington State Medical Association committee in 1988, when the inpatient utilization review (UR) program was established. This program provides preadmission medical necessity review for inpatient admissions, particularly related to surgical procedures. Earlier in 1988 L&I had established and published admission criteria for the inpatient medical treatment of back pain (for those that did not require surgery). Within one year of publishing these criteria, medical back admissions for the department fell by 60 percent. Surprisingly, a statewide sentinel effect was also seen in hospital discharge data. The inpatient UR program was originally contracted to an out-of-state vendor who used proprietary surgical criteria to establish medical necessity. Although these criteria are used nationally by insurance companies, they were felt to be inadequate in detail and specificity for L&I's purpose of assuring quality.

The first WSMA medical guidelines subcommittee meeting occurred in September 1988, in response to an L&I request to assist with development of guidelines for lumbar fusion. After three to four months of meetings, the subcommittee, which included several prominent spine surgeons from the Seattle area, presented a draft of guidelines for fusion to the full WSMA committee. In 1989, L&I published the fusion guidelines.

Since the publication of the medical back and fusion guidelines, 11 other guidelines have been established and published (Table 1). Although most have been guidelines for surgery, one recently developed guideline is for use of scheduled drugs for non-

[1]This work was done in full collaboration with the Washington State Medical Association Industrial Insurance Advisory Committee.

malignant pain. Another guideline, related to causality and treatment of carpal tunnel syndrome, has just been published.

The WSMA/L&I Medical Practice Guideline Process

The process used by the WSMA medical guidelines subcommittee is a combination of scientific evidence and community-based expert opinion. Although the consensus process is relatively informal, most aspects of the process for each guideline have been quite consistent, employing the following steps.

- Prioritization of guidelines
- Consensus development
- Formatting a decision-making algorithm
- Implementation
- Evaluation

Table 1. WSMA Practice Guidelines for Washington Workers' Compensation

Guideline	Date Published
Medical back admissions	1988
Lumbar arthrodesis	1989
Lumbar laminectomy	1990
Thoracic outlet release	1990
Cervical laminectomy	1991
Knee surgery	1991
Shoulder surgery	1991
Ankle/foot surgery	1992
Scheduled drug use	1992*
Lumbar arthrodesis	1994
Lumbar MRI	1994
Shoulder MRI	1994
Carpal tunnel surgery	1994

* WSMA Bulletin

PRIORITIZATION OF GUIDELINES

For the most part, prioritization has depended on 1) frequency of the problem, 2) cost, 3) poor outcomes or, 4) weak biologic plausibility. The lumbar fusion guideline, for example, was addressed first since no proprietary criteria for fusion were available. Other surgical guidelines were addressed because they are frequently performed (e.g., back, neck and knee). Both lumbar fusion and thoracic outlet surgery are relatively infrequent, but neither has strong clinical trial support nor clear biologic plausibility.

CONSENSUS DEVELOPMENT

Consensus development has generally taken place between the permanent members of the subcommittee (orthopedic surgeon, physiatrist, occupational medicine physician, neurologist, neurosurgeon) and *ad hoc* invited physicians who are clinical experts in the topic to be addressed. One hallmark of these discussions is that since few of the guidelines being discussed have a scientific basis, disagreement on specific points is common. Following the initial meeting on each guideline, subsequent meetings are only attended by permanent members unless information gathering from invited physicians is complete.

In order to reach consensus, the following assumptions are made.

1. The (surgical) guideline is meant to increase the proportion of surgical requests authorized for workers who truly require surgery, and to decrease the proportion of such authorizations among workers who do not fall within the consensus guideline.

2. The guideline is meant to be a gold standard for the majority of requests, but for the minority of workers who appear to fall outside of the guideline and whose complexity of clinical findings exceeds the specificity of the guideline, a further review by a specialty-matched physician is conducted.

3. The guideline is further refined after input from other community-based practicing physicians.

4. The guideline is evaluated to determine if it is having a beneficial effect.

5. The guideline-setting process will be iterative, that is, although initial guidelines may be quite liberally constructed, subsequent tightening of the guideline would occur as other national guidelines are set, or other scientific evidence (e.g., from outcomes research) becomes available.

Assumption number two is particularly important and warrants elaboration. The intention of the WSMA Medical Guidelines Subcommittee was to develop treatment guidelines that would be implemented in a nonadversarial way. The subcommittee tried to distinguish between clear-cut indications for procedures and indications that were questionable. The expectation was that when surgery was requested for a patient with clear-cut indications, the request would be approved by nurse consultants. However, if

such clear-cut indications were not present, the request would not be automatically denied. Instead, it would be referred to a physician consultant who would review the patient's file, discuss the case with the requesting surgeon, and make recommendations to the claims manager. The flexibility built into this decision making process was important in two ways. First, it enabled the subcommittee to develop surgical indications fairly quickly, since the members were aware that the indications would not be applied in a heavy-handed way. Second, it played a major role in legitimizing the work of the subcommittee in the eyes of practicing physicians in Washington.

FORMATTING A DECISION MAKING ALGORITHM

Once the principles of the guideline are reached by consensus, these principles are placed in a format consisting of and/or statements intended to aid professional nurse reviewers in deciding whether a particular surgical request falls within the guideline. (See lumbar laminectomy example, Appendix A).

IMPLEMENTATION

Most guideline development efforts, particularly at the federal level, stress dissemination of guidelines and hoped for change in physician behavior. The Institute of Medicine's report on development of practice guidelines (1992) differentiated between guidelines (intended for practitioners) and medical review criteria (intended to assess care).

It has become clear that, without a method of implementation, medical practice guidelines may be inconsistently and informally applied. Most of the surgical guidelines established by WSMA have been implemented in the context of the inpatient UR program. It has been critical in contract negotiations with UR vendors to specify that the vendor is willing to substitute WSMA-generated guidelines for less specific standards already in use by the company. More recently, the Department of Labor and Industries initiated an outpatient UR program, and this has allowed full implementation of guidelines related to outpatient procedures (e.g., carpal tunnel surgery, MRIs).

EVALUATION

The Department is developing a database sufficient to provide continuous evaluation of all newly implemented guidelines. Current evaluation efforts, dependent on retrospective vendor reports, are labor intensive and are not responsive enough to emerging needs. The new database could identify both provider indicators of outlying behavior, as well as worker-based health outcomes (e.g., time loss duration post surgery).

The Relationship of the WSMA/L&I Medical Practice Guideline Process to National and Statewide Guideline Efforts

Three specific types of guidelines may be differentiated. The first, a *point of service guideline,* is one which is used to determine if a specific medical intervention is warranted at a given point in time. Most of L&I's surgical guidelines would fall in this category. A second variety of guidelines is one which would be used to follow a patient over time, the guideline perhaps containing a number of red flags to indicate the risk for an adverse outcome. Such a guideline could be called a *longitudinal guideline,* one which helps in prospectively following patients. The forthcoming guideline for treating low back pain from the Agency for Health Care Policy and Research is an example. L&I's new guideline for use of scheduled drugs for nonmalignant pain would also fall in this category. A third type of guideline would relate to criteria for use of new technologies. Similar *technology evaluation guidelines* have been developed by the National Blue Cross/Blue Shield Association (Table 2), and would be more likely related to system-wide approaches to payment for new technologies whose efficacy is not clearly demonstrated. Technologies with proven efficacy would be dealt with as a point of service guideline.

Table 2. Blue Cross/Blue Shield National Association Technology Evaluation Criteria*

1.	The Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
2.	The technology must improve net health outcome.
3.	The technology must be as beneficial as any established alternatives.
4.	The improvement must be attainable outside the investigational setting.
5.	The technology must have final approval from the appropriate government regulatory bodies.

* Technologies must meet all five criteria to be recommended for coverage.

Woolf (1992) outlines four common approaches for developing practice guidelines that range from relatively unstructured, informal methods to very formal, structured approaches. Woolf characterizes the approaches as:

1. Informal consensus development, the most common approach, consists of a simple literature review and an unstructured consensus process.

2. Formal consensus development uses a structured approach to assess expert opinion and to reach agreement on recommendations.

3. Evidence-base guideline development bases recommendations directly on scientific evidence, and research findings are stressed over expert opinion.

4. Explicit guideline development is based on analyzing the potential benefits, harms, and costs of available interventions, estimating the possibility of the outcomes, and comparing the desirability of the outcomes based on patient preferences.

NATIONAL DEVELOPMENTS

The New England Medical Centers Institute for the Improvement of Medical Care and Health recently conducted a survey of eight prominent organizations that have innovative guideline development programs, (Audet, 1990). The organizations surveyed all have systematic approaches to guideline development and illustrate the spectrum of approaches described by Woolf. The various approaches provide a good point of reference for evaluating L&I's guideline development efforts.

Goals of guideline development. The goals of guideline development are fairly common across the organizations surveyed. All eight programs indicate that the goal of their program is to improve the quality and effectiveness of care. Six of the eight organizations surveyed stated that cost control is a secondary reason for developing guidelines.

Methods for developing practice guidelines. Guideline development methods vary considerably in terms of the approaches to reviewing current evidence, the use of national versus local experts, and consensus development methods.

Review of Current Evidence. The Harvard Community Health Plan, a leading HMO, relies on comparatively informal methods. The leader of a guideline effort conducts an informal literature review and distributes key papers to a consensus group. This method is similar to the approach used by L&I and is characterized by Woolf as *informal consensus*. In contrast, RAND and Value Health Sciences conduct an exhaustive review of the literature. The American College of Physicians uses an even more formal review process where experts are selected to summarize the literature in scholarly background papers. The papers include a description of methods used to analyze the background data from the literature.

Experts and Consensus Development. The Harvard Community Health Plan employs a nominal group process followed by a Delphi procedure which draws on local physicians who are likely users of the guidelines.

This is comparable to the approach used by L&I, although L&I involves fewer end-users. RAND and Value Health Sciences convene a group of nationally known experts who apply a rating system to the findings from extensive literature reviews, followed by a Delphi procedure. The American College of Physicians develops position papers which undergo review by all appropriate specialty societies.

Guideline Implementation. All eight organizations surveyed acknowledged they pay more attention to guideline development than they do to guideline implementation. Harvard Community Health Plan, Value Health Sciences, and MetroHealth employ computer software combined with monitoring and training programs to promote use of guidelines. In comparison, the American College of Physicians and the American Medical Association have no implementation strategy other than the dissemination of the guideline. L&I's application of guidelines varies; although most guidelines are rigorously applied through utilization review programs, the scheduled drug use

guideline has been widely disseminated by WSMA and used internally, but has not been formally implemented in a UR program.

Evaluation Research. Most organizations surveyed conceded that they devote the bulk of their resources to guideline development and commit few resources to evaluating guideline impacts. However, Harvard Community Health Plan is conducting a controlled study to evaluate the impacts of some of its guidelines. MetroHealth is also conducting a similar study. Value Health Sciences conducts hospital chart audits to determine the effectiveness of their preadmission review programs. However, evaluation efforts are considered relatively undeveloped by the survey authors. L&I's emphasis on evaluation puts the agency in a leading position relative to other model programs.

Summary. There is an apparent consensus on the goals of guideline development among the organizations surveyed, namely, to improve the quality of care and control costs. However, there is a spectrum of approaches to guideline development which vary from the relatively informal methods used by the Harvard Community Health Plan to the highly structured methods used by RAND, Value Health Sciences and the American College of Physicians. L&I's method tends to fall on the informal end of the spectrum and is most like the approach used by the Harvard Community Health Plan. However, this program is somewhat more developed than L&I's and may be a useful reference point for program enhancements. HCHP has been cited as a model program by Group Health Cooperative of Puget Sound.

Details of the Harvard Community Health Plan. The Harvard Community Health Plan (HCHP) is a 400,000 member HMO in Massachusetts. In 1986 it began what is now considered to be a prototype approach to developing practice standards. (Gottlieb, 1990) The program focuses on developing clinical algorithms for health problems that are commonly encountered by the HMO's practicing physicians. The algorithms outline a step-wise process for diagnosing and treating common health problems. The basis of the guideline formation process is to combine pertinent evidence from the medical literature, expert consultants, and HCHP practitioners to generate consensus algorithms.

HCHP initially developed a CME workshop to introduce practitioners to the program and encourage their involvement in algorithm development. Early concerns about *cookbook medicine* and worries about a top-down approach to developing and applying standards were addressed through open communication in the workshops. This apparently led to building support for the program among practicing physicians. A hallmark of both the HCHP and L&I programs is reliance on practicing clinicians to develop guidelines.

The program has completed and distributed 31 guidelines and has 50 ore underway. More than 300 physicians have been involved in the process. As the program has evolved, criteria have been developed for selecting topics for guideline development (Table 3). In addition, the program has outlined a thoughtful process for developing

guidelines (Table 4). The program is also experimenting with innovative education and training methods for implementing guidelines.

LOCAL DEVELOPMENTS IN WASHINGTON STATE

Group Health Cooperative of Puget Sound is currently developing a clinical guidelines program. They are looking at the HCHP guidelines program for direction. The First Choice Health Network is using automated guidelines known as *Patterns of Treatment* which were developed by Don Herrington, MD, of California. Another insurer in the state is also using this software. First Choice Network indicates that their initial attempts at sharing the comparative statistics produced by the software has been well received by their physicians. Furthermore, physicians appear to be using the profiles to evaluate their practice patterns in relation to their peers.

Table 3. Criteria for Choosing Clinical Algorithm Topics

- Common clinical conditions
- Unexplained variation in clinical practice (perceived or documented)
- Unexplained variation in utilization of limited or costly resources
- General clinical uncertainty or controversy
- Uncertain indications for risky or costly intervention
- Internal resource access or supply constraints
- Apparent risk management problem
- Introduction of new diagnostic test, therapeutic procedure or medication
- Quality of care problem perceived by patients, clinicians or managers

SOURCE: Audet, 1990

The 1990 Study of State Purchased Health Care recommended that the state establish a medical directorship that will work with local practitioners to establish practice standards. The study also recommended that state agencies develop methods to evaluate provider compliance with the standards and to provide feedback to

practitioners. These recommendations were superseded by the Washington Health Services Act of 1993, which authorized the new Health Services Commission and the Department of Health to promulgate rules in relationship to practice *indicators*, and that such *indicators* be based on the best available scientific evidence and consensus expert opinion.

Table 4. The Algorithm Development Process at HCHP

Project Planning

1. Identification of topic
2. Identification of intended users
3. Determination of suitability for *local* or *central* consensus
4. Identification and selection of group leader
5. Identification and selection of members of consensus group

Consensus Algorithm Development

6. Literature search and summary
7. *Seed algorithm* construction
8. Review of literature and seed algorithm by consensus group members
9. Brief algorithm and consensus development training
10. Consensus development via nominal group process and/or Delphi method

Algorithm Review

11. Identification of *essential nodes* for possible measurement
12. Identification and selection of *algorithm keeper*
13. Selection of date for next review and revision
14. Review and approval of algorithm

Implementation

15. Distribution of algorithm with request for feedback
16. Design of implementation strategies

SOURCE: Audet, 1990

Impact of the WSMA/L&I Medical Practice Guidelines

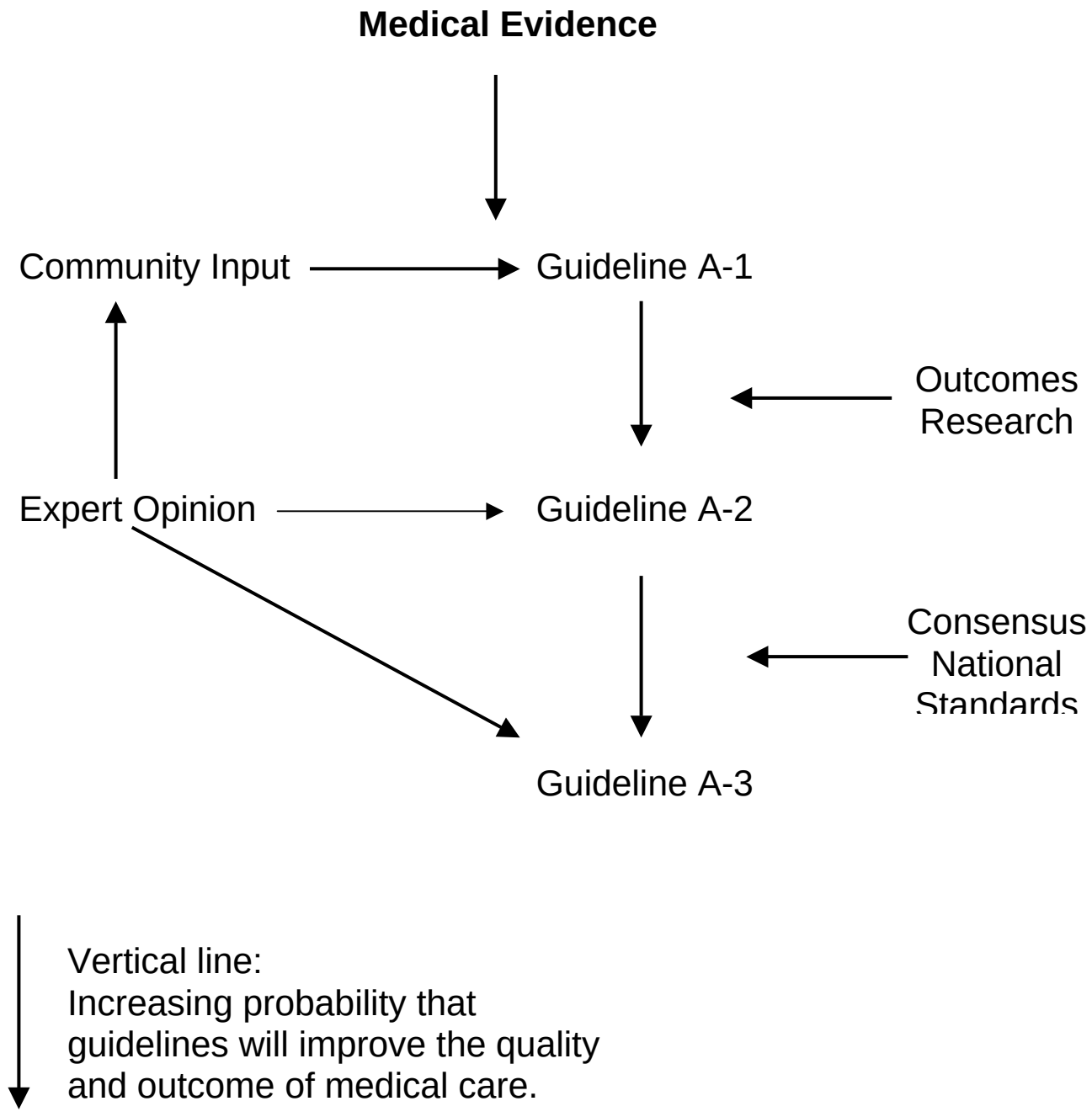
Plans are currently in place to evaluate the impact of the guidelines, and the Department has done a preliminary analysis of the impact of the original lumbar fusion guidelines. A 10-month experience in 1989 was reviewed. During this time, approximately 17 percent of requests for lumbar fusion were denied. Moreover, the workers in this group experienced claim resolution in the subsequent two years significantly more frequently (36%) than those who had fusion surgery (22%, $p < 0.05$). A more recent preliminary analysis of the fusion experience in 1991 revealed that the guideline had an initial significant effect but that this effect has only marginally increased with time. The implication was that a more specific standard would be in order at this time, and that any sentinel effect of inter-physician education had already been maximized.

Relationship to Outcomes Research

The guideline setting process should be iterative in nature, with increasingly specific guidelines produced as more scientific evidence becomes available (Figure 1). The Occupational Epidemiology and Health Outcomes program at the University of Washington, funded by Accident and Medical Aid fund monies, conducts outcomes research related to the L&I guidelines process. Outcome studies related to carpal tunnel surgery (Adams, 1994), lumbar fusion (Franklin, Haug, 1994), and thoracic outlet (Adams, 1994), lumbar fusion (Franklin, Haug, 1994), and thoracic outlet surgery (Franklin, Fulton-Kehoe, 1994), have been completed and have led to substantial changes in previously published guidelines. The principal example is the newly published guideline on lumbar fusion (Page 32), the most specific such guideline currently available. A new guideline on thoracic outlet surgery, not yet published, will require objective neurologic loss prior to approval of such surgery.

This iterative process stands in contrast to the method in some states of placing guidelines in regulation. Although such regulation could aid in the dissemination and quality oversight of guidelines, flexibility in creating updated guidelines might be limited.

Figure 1
WSMA/DLI Iterative Process for Setting Medical Guidelines



Legal Implications of the Guideline Process

Two principal legal questions have been addressed in regard to guideline development:

1. Are the physicians participating in the WSMA/L&I guideline development process protected from tort action?

2. Are practicing physicians who adhere to such guidelines protected from tort action?

In regard to question 1, an assistant attorney general's informal opinion in 1989 was that any physician participating on a voluntary (non-pay) basis in a medical committee established in RCW/WAC for quality assurance purposes would be defended by the full legal resources of the state. The principal successful action taken in the past against physicians participating in quality assurance decisions utilized federal antitrust law (Patrick decision, Oregon, 1986); however subsequent federal and state legislation protects physicians against similar use of federal antitrust law. (Curran, 1989)

Little precedent exists in regard to question 2. The state of Maine has passed a statute protecting physicians who utilize guidelines established by their peers. (Main statutes, 1989-91) This statute provides an affirmative defense for physicians in malpractice situations, who were complying with their specialty's guidelines. It is likely that similar statutory protection will occur as part of health care reform efforts in other states.

An additional legal issue relates to the weight of WSMA opinion at the Board of Industrial Insurance Appeals. If an individual request for surgery does not meet WSMA's guidelines, and is rejected by L&I, it is theoretically possible that such denial of surgery could be overturned at the Board. This fundamental tension between the authority of L&I to implement WSMA community-based treatment guidelines, and the individual workers' or provider's right to appeal such decisions to the Board, will need to be resolved if guideline use in the context of worker's compensation is to be a successful effort. A related underlying assumption of the WSMA guideline process has been that specific indications for surgery ought to be biologic and not based in the adversarial relationships classically engendered in worker's compensation.

Technology Assessment

The assessment of the efficacy of emerging technologies has proved particularly vexing for L&I and other state agencies. The principal problem lies in a dual standard for approval of drugs and new devices at the FDA. Drugs must be proven to be both safe and effective when they are approved for use. New devices, on the other hand, may receive "premarket approval" based on much less stringent safety and efficacy data. Although the intent of this dual standard was to foster development of new technologies, the real effect is that relatively untested devices may gain credibility within the medical community. The Safe Medical Devices Act of 1990 (PL101-629) (DHHS FDA, 1991) gives the FDA more authority to monitor the use of premarket approved devices. For example, hospitals may now be audited for adverse events related to devise use.

Nonetheless, the responsibility for reimbursement for what are essentially investigational devices is left to third party payers. Criteria similar to those used by the Blue Cross/Blue Shield National Association (Table 2) or criteria based on improvement in net health outcome could help reconcile the worker's compensation "palliative vs. curative care" issues.

The relationship of the WSMA guideline work to Board of Industrial Insurance Appeals activity is particularly critical in the technology area. One example is use of the epidural (spinal) stimulator to treat chronic low back and leg pain. On three separate occasions between November 1990 and June 1991, the WSMA Industrial Insurance Committee reviewed safety and efficacy data on this device and voted unanimously to urge L&I not to authorize its use in any case. At least 3 cases appealing the nonauthorization have appeared before the Board, all of which have been upheld in the Department's favor. However, two of the cases were reversed at Superior Court. Although these higher court decisions are not precedent setting, L&I is working to create new regulations that would strengthen the amount of scientific evidence that would be required to justify coverage of emerging procedures and diagnostic tests. Such regulations could further clarify the authority of the WSMA guidelines committee.

A final example of the new technology dilemma facing L&I is the use of pedicle screw fixation devices by orthopedic surgeons to assist in achieving solid lumbar fusion. Most of the fixation devices in use today are not approved for use by the FDA, and research at the University of Washington has suggested adverse outcomes from their use. (Franklin, Haug, 1994) Nonetheless, nearly one-half of all fusion patients have received this device as an adjunct to lumbar fusion surgery. The new fusion guideline (Page 32) contains specific language that must be incorporated into informed consent that explicitly states the experimental nature of these devices.

Future Research and Recommendations

The hallmarks of the WSMA/L&I process for setting medical guidelines are that it is 1) driven by community-based expert opinion, 2) designed to be responsive to end users (physicians, L&I), 3) primarily based (implemented) in prospective review programs and 4) flexible enough to be iterative in nature. The iterative nature of the process is crucial in allowing for continuous improvement of guidelines based on emerging scientific evidence and national consensus efforts (Figure 1). Building on these strengths, the following recommendations should be considered:

- The WSMA/L&I guideline process has been endorsed by a formal labor-management consensus process, the statutory Workers Compensation Advisory Committee. Similar endorsement in other states could improve understanding of the value of practice guidelines in workers compensation.

- Enhancements to the current process should include:

  - Development of methodologies to maximize community-based physician input and support
  - Expansion of the capacity of L&I prospective review programs to implement longitudinal guidelines.
  - Better coordination of case management of injured workers whose care does not fall within established medical guidelines.
  - Formalization of criteria for prioritizing guidelines to meet both short and long term needs.
  - Better design of internal evaluation procedures to determine if guidelines are improving net health outcomes.

- In order to maximize limited resources, increased networking, demonstration projects and sharing of expertise should be pursued with other state and federal agencies and professional societies which are involved in the guideline development and technology assessment processes.

- The relationship of the WSMA/L&I guideline process to existing or emerging guidelines should be clarified in policy. To the extent possible in the future, guidelines in use by utilization management vendors should be available for review by the WSMA medical guidelines committee. In most cases, a WSMA/L&I guideline should be used rather than more generic or nonspecific guidelines already in use by the vendor. If a guideline is established by a nationally recognized group (e.g., RAND Corporation, Agency for Health Care Policy and Research) that a) exceeds the specificity of a WSMA/L&I guideline, b) is more clearly based on stronger scientific evidence, c) has broader consensus, and d) is implementable, then such a guideline could replace an existing WSMA/L&I guideline. However, even in this case, acceptance by the WSMA medical guidelines committee would be critical.

- For new technologies which have received premarket approval by the FDA, but whose efficacy data is unclear, the following requirements for requesting physicians are recommended:

  - Physicians should have Institutional Review Board approval from their own institution (e.g., hospital, HMO) to perform the procedure
  - The physician should be part of a formal data collection effort
  - The physician should supply data to L&I and the WSMA medical guidelines committee sufficient to meet the Blue Cross/Blue Shield criteria for technology assessment.

  For those technologies which **do not** have FDA approval, but which are in use in the community, the above criteria should apply and L&I should require that appropriate informed consent language be included in guidelines (see Page 33, Lumbar Fusion Guidelines).

- The WSMA medical guidelines committee should strive to include principles of disability prevention and management in their guideline process.

- The interface between the WSMA/L&I guideline process and the role of the Board of Industrial Insurance Appeals should be clarified, perhaps in statute. At a minimum, medical expertise resident on the board could help clarify disputes in regard to use of community-based medical guidelines. The key issue here is not whether or not the WSMA Industrial Insurance Advisory Committee has the authority to establish medical guidelines for L&I, but rather whether the facts of the worker's case were properly interpreted **within** the context of the guideline.

- Clear definition of key terms should be made in WAC and policy. For WAC these could include clearer definition of *experimental*, new - *technology*, and *net health* benefit. In policy, this could include *guidelines, standards,* and other key terms.

- L&I should, along with other state agencies, develop a strategic plan to a) enhance legal protection for peer reviewers and b) allow compliance with state mandated guidelines to be an affirmative defense in malpractice situations.

- The capacity of the University of Washington and L&I to conduct outcomes research on worker's compensation specific health issues should be enhanced.

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GUIDELINE FOR HOSPITALIZATION FOR LOW BACK PAIN

The following guideline replaces Criteria for Non-Surgical Hospital Admission for Acute and Chronic Low Back Pain published in Provider Bulletin 88-09.

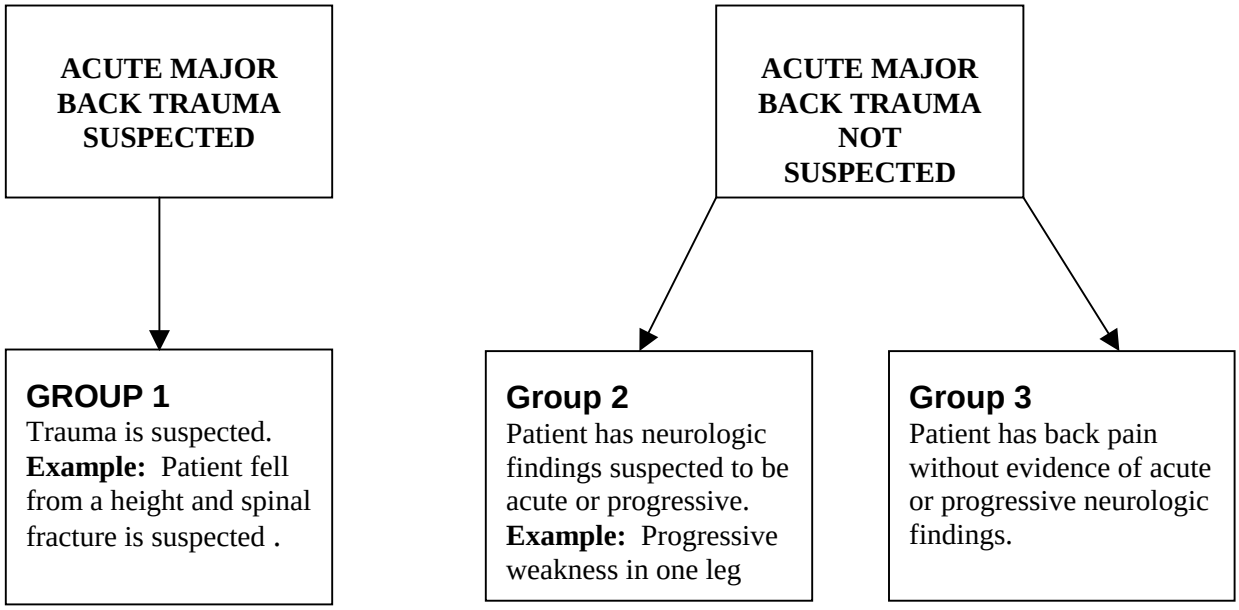
Changes in Practice Patterns:

Several years ago it was fairly common for physicians to hospitalize patients for medical management of low back pain. Typically, hospitalized patients were treated with bed rest, traction, and medication.

The frequency with which low back pain patients are hospitalized for medical management has dropped dramatically during the past ten years. This trend applies to both the injured worker population and other patient groups. For example, in 1986 there were approximately 1500 hospitalizations for medical management of low back pain among L&I patients; in 1996, the corresponding number was about 70.

The present guidelines reflect the current consensus that hospitalization is rarely needed for patients with low back pain.

CLASSIFICATION OF PATIENTS WITH LOW BACK PAIN



Guidelines for the management of these various groups or categories of medical problems are described on the following pages.

Date Introduced: June 1998

CLINICAL FEATURES	PREADMISSION EVALUATION AND TREATMENT	HOSPITAL ADMISSION CRITERIA	POST-ADMISSION MANAGEMENT
GROUP 1: Acute Major Trauma Suspected A) Back injury occurred within the past 7 days **AND** B) A major trauma was sustained (e.g. fall from a height, or back crushed by heavy object). **AND** C) Examining physician documents or suspects acute spinal fracture, spinal cord injury or nerve root injury.	Individualized	Individualized	Individualized
GROUP 2: Acute Major Back Trauma Not Suspected; Patient has Neurologic Findings Suspected to be Active or Progressive A) No history of recent major injury **AND** B) Patient complains of symptoms suggesting acute or progressive neurologic deficit. Typically these include: 1) Progressive weakness or numbness in one leg (and occasionally both legs) **OR** 2) Loss of control of bowel or bladder function **OR** 3) Progressive numbness in the perineal region **AND** C) The examining physician indicates that the patient has (or probably has) an acute or progressive neurologic deficit	A) Outpatient setting: Evaluation and treatment is individualized. B) Emergency Department Setting: 1) Advanced diagnostic imaging may be indicated when a patient in Group 2 comes to the Emergency Department. 2) An attempt to reach the patient's attending physician should always be made before an emergency department MD decides to order advanced imaging studies. (The attending physician is in the best position to evaluate the patient's clinical presentation and judge the usefulness of imaging studies). 3) If an imaging study is done and does NOT demonstrate an acute, lesion, for which surgery is indicated, the patient should be managed like a patient in Group 3. The patient should be discharged unless he/she is unable to perform ADLs at home.	A) If a patient has a new or progressive neurologic deficit, he/she may be hospitalized in order to facilitate surgical decision-making, to provide close observation of further progression or to help the patient compensate for neurological deficits (e.g. to determine whether the patient needs to learn intermittent catheterization). B) If a patient does NOT have a new or progressive neurologic deficit, he/she should be treated like a patient in Group 3. The only valid reason for hospitalization is that he/she cannot manage basic ADLs at home. C) If a patient is admitted through an emergency department, the decision to admit should be made with the concurrence of the attending physician, unless the attending physician cannot be reached.	A) *Duration of hospitalization should be brief*. The great majority of Group 2 patients who are admitted to a hospital can be discharged in 1-3 days (if spine surgery is not performed). B) Treatment Plan Goals 1) General Strategy – It is crucial to assess the patients' ability to perform ADLs and to identify environmental barriers to return home. a) An assessment of these factors should begin immediately upon admission. A list of barriers to discharge should be noted in the patient record. b) The ability of the patient to perform ADLs should be measured serially, e.g., can the patient ambulate to the bathroom? c) Discharge planning should begin immediately, for example: the patient's significant other should be contacted and problem solving should be undertaken regarding practical problems such as the ability to get food and ambulate to the bathroom in the home. 2) Pain Management – Review potential to benefit

CLINICAL FEATURES	PREADMISSION EVALUATION AND TREATMENT	HOSPITAL ADMISSION CRITERIA	POST-ADMISSION MANAGEMENT
			from nonsteroidals, antidepressants, opiates. **NOTE:** The Department of Labor and Industries does not cover epidural or intrathecal administration of opiates except in the peri-operative period. 3) Management of Neurological Deficits – a patient may need help with bladder catheterization or may need a brace for his/her leg. C) Diagnostic Imaging, Physician Consultants and Surgical Planning – Individualized. D) **NOTE:** Prolonged bed rest usually does more harm than good in a patient with low back pain. Admission for the purpose of bed rest is not acceptable.
GROUP 3: Acute Major Back Trauma Not Suspected; Patient Has Back Pain Without Evidence of Acute or Progressive Neurologic Findings A) No history of recent major trauma. **AND** B) Patient complains of back pain with or without symptoms in the legs. Occasionally patients will complain mainly of symptoms in the legs but **the evaluating physician concludes that symptoms are not caused by lumbar radiculopathy** **AND** C) No evidence of acute or progressive neurologic deficit.	A) When the attending physician initiates hospitalization from an outpatient setting: 1) The attending physician must document that he/she has given the patient an adequate trial of oral medication to control pain and that the patient has made a genuine attempt to manage ADLs at home. B) When hospitalization is initiated from an emergency room: **NOTE:** most admissions for back pain start with an injured worker going to the emergency department. 1) Advanced imaging is RARELY indicated. Advanced imaging should be ordered ONLY with the concurrence or the patient's attending physician.	A) The only valid reason for hospitalizing a patient is that he/she cannot manage basic ADLs at home. Example, the patient lives alone and is unable to get to the bathroom. B) If a patient is admitted through the emergency department, the decision to admit should be made with the concurrence of the attending physician, unless the attending physician cannot be reached.	A) *Duration of hospitalization should be brief.* The great majority of Group 3 patients who are admitted to a hospital can be discharged in less than 24 hours. B) *Treatment Plan Goals* 1) General Strategy – It is crucial to assess the patient's ability to perform ADLs and to identify environmental barriers to return to the home. a) An assessment of these factors should begin immediately upon admission. A list of barriers to discharge should be noted in the patient record b) The ability of the patient to perform ADLs should be measured serially – e.g., can the patient ambulate to the bathroom? c) Discharge planning should begin immediately, for example: the patient's significant other should be contacted and problem solving should be undertaken regarding

CLINICAL FEATURES	**PREADMISSION EVALUATION AND TREATMENT**	**HOSPITAL ADMISSION CRITERIA**	**POST-ADMISSION MANAGEMENT**
			practical problems such as the ability to get food and ambulate to the bathroom in the home. 2) Pain Management – Review potential to benefit from nonsteroidals, antidepressants, opiates. **NOTE:** The Department of Labor and Industries does not cover epidural or intrathecal administration of opiates except in the peri-operative period). Physical Activity – The patient should receive aggressive physical therapy at least twice per day. 3) Diagnostic Imaging and Physician Consultants a) These rarely need to be done while a patient is in the hospital. b) The patient's hospital stay should not be prolonged simply to facilitate imaging or consultation while he/she is still in the hospital. The patient should be discharged as soon as he/she is able to manage basic ADLs. Imaging and consultation can be done as an outpatient. C) **NOTE:** Admission for the purpose of bed rest or traction alone is not acceptable. D) A patient should not be admitted to a hospital that does not have the capacity to assess ADLs, develop a treatment plan, & provide physical therapy within the first 24 hours.

Cauda Equina

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
LUMBAR: LAMINECTOMY, DISCECTOMY,	Not Applicable	Sudden onset or rapid progression of sensory symptoms **AND**	Acute Progressive neurological deficit that is either bilateral or involves multiple neurological levels **AND**	Demonstrates a large lesion producing central stenosis with tight obstruction Tests include: CT Scan OR MRI OR Myelogram

Date Introduced: January 1991

Criteria for Knee Surgery

PROCEDURE	Clinical Findings				
	SUBJECTIVE		OBJECTIVE		IMAGING
ANTERIOR CRUCIATE LIGAMENT (ACL) REPAIR	(Pain alone is not an indication) Instability of the knee; described as "buckling or giving way" --- Supportive findings: Significant effusion at the time of injury AND/OR Description of injury indicates a rotary twisting or hyperextension occurred	**AND**	Positive Lachman's sign --- Supportive findings: Positive pivot shift AND/OR Positive anterior drawer AND/OR Positive KT 1000 >3-5 mm = +1 >5-7 mm = +2 >7 mm = +3	**AND**	Positive findings with: Arthrogram OR MRI OR Arthroscopy
PATELLA TENDON RE-ALIGNMENT OR MAQUET PROCEDURE	Rest-sitting pain	**AND**	Pain with patellar/ femoral movement AND/OR Recurrent dislocations	**AND**	Recurrent effusion AND Patella apprehension AND Synovitis with or without crepitus AND Lateral tracking AND Increased Q angle>15 degrees
KNEE JOINT REPLACEMENT	Limited range of motion AND Night pain of the joint AND No relief of pain with conservative care	**AND**	Significant loss or erosion of cartilage to the bone	**AND**	Positive findings with Sanding films OR Arthroscopy
(If 2 of the 3 compartments are affected, a total joint replacement is indicated. If only 1 compartment is affected, a unicompartmental or partial replacement is indicated.)					

Reference: Provider Bulletin 91-01; Date Introduced: January 1991

Criteria for Cervical Surgery
Related to Entrapment of a Single Cervical Nerve Root

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
CERVICAL LAMINECTOMY DISCECTOMY LAMINOTOMY FORAMINOTOMY WITH OR WITHOUT FUSION, EXCLUDING FRACTURE	6-8 weeks minimum For example: - physical therapy - non-steroid anti-inflammatory agents - cervical traction	Sensory symptoms in a dermatomal distribution (could include: radiating pain, paresthesia, tingling, burning or numbness)	Dermatomal sensory deficit OR Motor deficit OR Reflex changes OR Positive EMG	Abnormal test results that correlate with the level of nerve root involvement consistent with subjective and objective findings. Tests include: CT scan OR MRI OR Myelogram

AND AND AND

Cases to be referred to a physician advisor:

- Repeat surgery at same level
- Request for surgery at the C3-4 level
- Requests for surgery with signs and symptoms indicating myelopathy

When requesting authorization for decompression of multiple level nerve roots, each level is subject to the criteria.

Date Introduced: May 1991

Criteria for Entrapment of a Single Lumbar Nerve Root

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
LUMBAR: LAMINECTOMY, LAMINOTOMY, DISCECTOMY, MICRO- DISCECTOMY, FORAMINOTOMY	Failure to improve with four weeks minimum **AND** For example: - Physical therapy - Non-steroidal anti-inflammatory agents - Traction	Sensory symptoms in dermatomal distribution may include: Radiating pain, burning, numbness, tingling or paresthesia of lower extremity	Dermatomal sensory deficit **OR** OR Motor deficit (e.g., foot drop or quadriceps weakness) OR Reflex changes OR Positive EMG	**AND** Abnormal test results that correlate with the level of nerve root involvement consistent with subjective and objective findings. Tests include: CT Scan OR MRI OR Myelogram

Requests for authorization to treat lateral or central spinal stenosis not accompanied by nerve root entrapment or the necessity of arthrodesis will be reviewed by a Physician Adviser.

Date Introduced: March 1992

Criteria for Ankle/Foot

PROCEDURE	CONSERVATIVE CARE		Clinical Findings		
			SUBJECTIVE	OBJECTIVE	IMAGING
FUSION - ANKLE - TARSAL - METATARSAL TO TREAT NON- OR MAL-UNION OF A FRACTURE OR TRAUMATIC ARTHRITIS SECONDARY TO ON THE JOB INJURY TO THE AFFECTED JOINT	Immobilization which may include: Casting, bracing, shoe modification or other orthotics OR Anti-inflammatory medications	**AND**	Pain including that which is aggravated by activity and weight-bearing AND Relieved by Xylocaine injection	**AND** Malalignment AND Decreased range of motion	**AND** Positive x-ray confirming presence of: - Loss of articular cartilage (arthritis) OR - Bone deformity (hypertrophic spurring, sclerosis) OR - Non or mal-union of a fracture Supportive imaging could include: Bone scan (for arthritis only) to confirm localization OR MRI OR Tomography

- Requests for intertarsal or subtalar fusion will be referred to Physician Adviser

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Date Introduced: March 1992

Criteria for Ankle Continued

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
LATERAL LIGAMENT ANKLE RECONSTRUCTION FOR CHRONIC INSTABILITY OR ACUTE SPRAIN/STRAIN INVERSION INJURY	Physical Therapy - immobilization with support cast or ankle brace - Rehab program For either of the above, time frame will be variable with severity of trauma	For chronic: - Instability of the ankle Supportive findings: - Complaint of swelling For acute: - Description of an inversion AND/OR Hyperextension injury, ecchymosis, swelling	For chronic: Positive anterior drawer For acute: - Grade 3 injury (lateral injury) AND/OR Osteochondral fragment AND/OR Medial incompetence AND Positive anterior drawer	Positive stress x-rays identifying motion at ankle or subtalar joint. At least 15° lateral opening at the ankle joint. OR Demonstrable subtalar movement AND Negative to minimal arthritic joint changes on x-ray

AND AND AND

- Requests to use prosthetic ligaments will not be authorized

- Requests for any plastic implant will be referred to a Physician Adviser for review

- Requests for calcaneous osteotomies will be referred to a Physician Adviser for review

Criteria for MRI of the Lumbar Spine

INDICATIONS FOR MRI OF THE LUMBAR SPINE

- Any neurologic deficit, evidence of radiculopathy, cauda equina compression (e.g., sudden bowel/bladder disturbance).

OR

- Suspected systemic disorder, i.e., to r/o metastatic or infectious disease.

OR

- Localized back pain with no radiculopathy (leg pain), clinical history of lumbar sprain or strain, and failed 6-week course of conservative care.

INDICATIONS FOR REPEAT MRI OF THE LUMBAR SPINE

- Significant change in clinical finding, i.e., new or progressive neurological deficit.

NOTE: The primary physician is strongly encouraged to coordinate with a subspecialist: i.e., a board certified spine specialist, orthopedist or radiologist, before ordering a repeat MRI of the lumbar spine.

Date Introduced: January 1994

Criteria for Shoulder Surgery

A request may be appropriate for ↓	If the patient has ↓	AND the diagnosis is supported by ↓ ↓ ↓			AND this has been done (if recommended) ↓
SURGICAL PROCEDURE	**DIAGNOSIS**	**CLINICAL FINDINGS**			**CONSERVATIVE CARE**
		SUBJECTIVE	**OBJECTIVE**	**IMAGING**	
Rotator cuff repair (CPT 23410, 23412, 23420)	**Full Thickness Rotator Cuff Tear** **AND** Cervical pathology and frozen shoulder syndrome have been ruled out	Shoulder pain and inability to elevate the arm; Tenderness over the greater tuberosity is common in acute cases	Patient may have weakness with abduction testing; May also demonstrate atrophy of shoulder musculature; Usually has full passive range of motion.	Conventional x-rays, AP, and true lateral or axillary view **AND** Gadolinium MRI, Ultrasound, or Arthrogram shows positive evidence of deficit in rotator cuff	Not required
Rotator cuff repair CPT 23410, 23412, or 23420) **OR** **Anterior acromioplasty** [1] (CPT 23130, 23415, 29826)	**Partial Thickness Rotator Cuff Repair** **OR** **Acromial Impingement Syndrome** (80% of these patients will get better without surgery) [1]	Pain with active arc motion 90-130 ° **AND** Pain at night; Tenderness over the greater tuberosity is common in acute cases.	Weak or absent abduction. May also demonstrate atrophy **AND** Tenderness over rotator cuff or anterior acromial area **AND** Positive impingement sign and temporary relief of pain with anesthetic injection (diagnostic injection test)	Conventional x-rays, AP, and true lateral or axillary view **AND** Gadolinium MRI, Ultrasound, or Arthrogram shows positive evidence of deficit in rotator cuff	Recommend 3-6 months: Three months is adequate if treatment has been continuous, six months if treatment has been intermittent. Treatment must be directed toward gaining full ROM, which requires both stretching and strengthening to balance the musculature.
Treatment of acromioclavicular dislocation, **acute or chronic** (CPT 23550)	**Shoulder AC Joint Separation**	Pain with marked functional difficulty	Marked deformity	Conventional x-rays Show Grade III+ separation	Recommend at least 3 months. Most patients with grade III AC dislocations are best treated non-operatively.
Partial claviculectomy (includes Mumford procedure) (CPT 23120, 29824)	**Post traumatic Arthritis of AC Joint**	Pain at AC joint; aggravation of pain with shoulder motion or carrying weight **OR** Previous Grade I or II AC separation	Tenderness over the AC joint; Most symptomatic patients with partial AC join separation have a positive bone scan **AND/OR** Pain relief obtained with an injection of anesthetic for diagnostic therapeutic trial	Conventional films show either: (a) Post traumatic changes of AC joint, OR (b) Severe DJD of AC joint, OR (c) Complete or incomplete separation of AC joint. **AND** Bone scan is positive for AC joint separation	At least 6 weeks of care directed toward symptom relief prior to surgery. Surgery is not indicated before 6 weeks.

[1] Neer, C. S. Anterior acromioplasty for the chronic impingement syndrome in the shoulder: a preliminary report. Journal of Bone & Joint Surgery, American Volume. 54(1):41-50, 1972 (Jan.)

Reference: Provider Bulletin 02-01; Date Introduced: March 2002

Criteria for Shoulder Surgery -- Continued

A request may be appropriate for ↓	If the patient has ↓	AND the diagnosis is supported by ↓ ↓ ↓			AND this has been done (if recommended) ↓
SURGICAL PROCEDURE	**DIAGNOSIS**	**CLINICAL FINDINGS**			**CONSERVATIVE CARE**
		SUBJECTIVE	**OBJECTIVE**	**IMAGING**	
Capsulorrhaphy or Bankart procedure (CPT 23450, 23455, 29806)	**Recurrent Glenohumeral Dislocations**	History of multiple dislocations that inhibit activities of daily living	At least one of the following: Positive apprehension findings; OR Injury to the humeral head; OR Documented dislocation under anesthesia	Conventional x-rays, AP and true lateral or axillary view	None required
Tenodesis of Long Head of Biceps (CPT 23430) Consideration of tenodesis should include the following: Patient should be a young adult; Not recommended as an independent stand alone procedure There must be evidence of an incomplete tear	**Incomplete Tear or raying of the Proximal Biceps Tendon** The diagnosis of fraying is usually identified at the time of acromioplasty or rotator cuff repair so may require retrospective review	Complaint of more than "normal" amount of pain that does not resolve with attempt to use arm. Pain and function fails to follow normal course of recovery.	Partial thickness tears do not have the classical appearance of ruptured muscle.	Same as that required to rule out full thickness rotator cuff tear: Conventional x-rays, AP, and true lateral or axillary view **AND** Gadolinium MRI, Ultrasound, or Arthrogram shows positive evidence of deficit in rotator cuff	None required
Tenodesis of Long Head of Biceps (CPT 23430)	**Complete Tear of the Proximal Biceps Tendon**	Pain, weakness, and deformity	Classical appearance of ruptured muscle.	Not required	Surgery almost never considered in full thickness ruptures.
Reinsertion of Ruptured Biceps Tendon (CPT 24342)	**Distal Rupture of the Biceps Tendon**	All should be repaired within 2-3 weeks of injury or diagnosis. A diagnosis is made when the physician cannot palpate the insertion of the tendon at the patient's antecubital fossa. Surgery is not indicated if 3 or more months have elapsed.			
Diagnostic Arthroscopy (CPT 29805)	**Shoulder Arthroscopy for Diagnostic Purposes**	Most orthopedic surgeons can generally determine the diagnosis through examination and imaging studies alone. Diagnostic arthroscopy should be limited to cases where imaging is inconclusive and acute pain or functional limitation continues despite conservative care. Shoulder arthroscopy should be performed in the outpatient setting. Requests for authorization of this procedure in the inpatient setting will be reviewed by a peer physician. If a rotator cuff tear is shown to be present following a diagnostic arthroscopy, follow the guidelines for either a full or partial thickness rotator cuff tear.			

Guidelines For Lumbar Fusion (Arthrodesis)

I. The purpose of these guidelines is:

A. To serve as an instructional aid for physicians when treating injured workers who present with low back pain and associated symptoms that have developed in the context of routine work activity, and who have no evidence of spinal fracture.

B. To provide utilization review nurses with the information necessary to make recommendations about the medical necessity and clinical appropriateness of spinal fusions.

Exception: These guidelines do not apply to requests for fusion to treat patients with a spinal fracture or dislocation, spinal infection, or spinal deformity, (e.g. one related to degenerative scoliosis).

II. Conservative care (consisting of all the following) should be tried first.

A. The patient should have at least three months of conservative therapy for low back pain, which predominantly emphasizes physical reconditioning.

B. The surgeon requesting the lumbar fusion should have personally evaluated the patient on at least two occasions prior to requesting the fusion.

Exception: If the patient has a progressive neurological deficit, both A and B above can be waived.

III. If conservative care has failed to relieve symptoms and the patient has had no prior surgery, lumbar fusions should be considered only if the patient has one or more of the following:

A. Mechanical (non-radicular) low back pain with instability;

Instability of the lumbar segment is defined as at least 4mm of anterior/posterior translation at L3-4 and L4-5, or 5mm of translation at L5-S1 or 11 degrees greater end plate angular change at a single level, compared to an adjacent level. Adequate flexion/extension views should be taken utilizing techniques that minimize the potential contribution of hip motion to perceived lumbar flexion or extension.

Note: Only single level fusions will be approved for patients with no prior spinal surgery.

Reference: Provider Bulletin 01-05; Date Introduced: June 2001

B. Spondylolisthesis exists with one or more of the following:

1. Objective signs/symptoms of neurogenic claudication *OR*
2. Objective signs/symptoms of unilateral or bilateral radiculopathy, which are corroborated by neurologic examination and by MRI or CT (with or without myelography) *OR*
3. Instability of the lumbar segment as defined above in section III-A.

IV. If conservative care has failed to relieve symptoms and the patient has had a prior laminectomy, diskectomy, or other decompressive procedure at the same level, lumbar fusion should be considered only if the patient has one or more of the following:

A. Mechanical (non-radicular) low back pain with instability (as defined above in Section III-A) at the same or adjacent levels *OR*
B. Mechanical (non-radicular) low back pain with pseudospondylolisthesis, rotational deformity or other condition leading to a progressive (measurable) deformity *OR*
C. Objective signs/symptoms compatible with neurogenic claudication or lumbar radiculopathy that is supported by MRI or CT (with or without myelography) and by a detailed clinical neurological examination *OR*
D. Evidence from a post-laminectomy structural study of either:
    1. 100% loss of facet surface area unilaterally, *OR*
    2. 50% combined loss of facet surface area bilaterally

V. If conservative care has failed to relive symptoms and the patient has had a prior fusion at the same level, lumbar fusion should be considered only if the patient has one or more of the following:

A. Psuedarthrosis with or without hardware failure, confirmed by objective evidence of pseudarthrosis (e.g. abnormal thin slice CT scan)
B. Neurogenic claudication supported by either MRI, CT, or myelography
C. Lumbar radiculopathy supported by either MRI, CT, or myelography, or supported by a detailed clinical neurological or neurosurgical examination.

VI. If conservative care has failed to relieve symptoms and the patient has had a prior fusion at a level adjacent to the new one being considered, lumbar fusion should be considered only if the patient meets the same criteria as described for patients with no prior history of spine surgery (see section III above).

VII. Contraindications for lumbar fusions, even when patients meet the criteria described in sections III, IV, V, and VI above.

A. Absolute contraindications
    1. Lumbar fusion is not indicated with an initial laminectomy/diskectomy related to unilateral compression of a lumbar nerve root.

B. Relative contraindications

1. Severe physical de-conditioning
2. Current smoking
3. Multiple level degenerative disease of the lumbar spine
4. Greater than 12 months of disability (time-loss compensation benefits) prior to consideration of fusion
5. No evidence of functional recovery (return to work) for at least six months following the most recent spine surgery
6. Psychosocial factors that are correlated with poor outcome, such as:
    a. History of drug or alcohol abuse
    b. High degrees of somatization on clinical or psychological evaluation
    c. Presence of a personality disorder or major psychiatric illness
    d. Current evidence of factitious disorder

VII. When the physician wants to proceed with a lumbar fusion request:

A. The physician should be aware of the following research based findings*:
1. The chance of an injured worker no longer being disable 2 years after lumbar fusion is only 32%.
2. More than 50% of workers who received lumbar fusion through the Washington workers' compensation program felt that both pain and functional recovery were no better or worse after lumbar fusion.
3. The overall rate of re-operation within 2 years for all fusions is approximately 23%.
4. Smoking at the time of fusion greatly increases the risk of pseudarthrosis.
5. Pain relief, even when present, is not likely to be complete.
6. The use of spine stabilization hardware (metal devices) in Washington workers nearly doubled the chances of having another surgery.

B. The operating surgeon should follow the lumbar fusion patient at least every two months for the first six postoperative months. At the six month examination, if the patient is still experiencing significant pain, a face to face evaluation should be conducted, which includes all of the following elements:
1. Neurologic examination
2. This slice CT to rule out pseudarthrosis
3. Repeat flexion-extension films to rule out instability (as defined in III-A)

If new objective neurologic signs are absent, and if there is no objective evidence of fusion failure, the patient may have reached maximum medical improvement and an impairment rating (permanent partial disability (PPD) assessment) may be appropriate.

C. Prior to lumbar fusion, clinical psychological or psychiatric assessment should be performed on all patients who meet the lumbar fusion criteria and who have been receiving time-loss compensation benefits. This assessment is intended to help the requesting surgeon identify specific psychological risk factors for chronic disability that may be barriers to recovery following lumbar fusion.

D. All intraoperative determinations of instability that lead to fusion must be clearly documented at the time, and (if requested by L&I) subsequently discussed with a peer surgeon.
E. Although adding to the clinical database, provocative discography, diagnostic facet joint injections, and pain relief during the use of a rigid spinal brace are not definitive indications for fusion.
F. Anterior Lumbar Interbody Fusion (ALIF), if indicated, should be done only in conjunction with a posterior stabilization procedure.

Note: Prior to surgery, the physician should discuss with the patient, the information provided on the attached form (see next page). After discussing these details, both the physician and patient should sign at the bottom of the form. The form should be kept in the patient's medical records at the requesting surgeon's office.

What You Should Know About Lumbar Fusion Surgery

Labor & Industries (the department) has created this information form so you will know how lumbar fusion surgery may affect your health and recovery. The department requires your doctor to discuss this information with you before the surgery in order to make the best decision possible. After you have read and discussed this information, both you and your doctor should sign your names at the end of this form. **This is NOT a surgical consent form.**

A study* conducted by Labor & Industries at the University of Washington showed that in Washington workers:

- About 2/3 of the workers who receive a lumbar fusion are still disabled two years after the surgery.
- More than half of the workers who received lumbar fusion felt that both their pain and ability to function were no better or worse after the surgery.
- Almost one quarter of the workers who had fusion surgery were operated on again within two years.
- Smoking at the time of fusion greatly increases the risk of failed fusion.
- The use of spine stabilization hardware (metal devices) in Washington workers nearly doubled the chances of having another surgery.
- Pain relief, even when present, is not likely to be complete.

In addition:

- Smoking at the time of fusion greatly increases the risk of fusion failure.
- Pain relief after fusion, even when it occurs, is not likely to be complete.

You should also know the department's expectations:
If the department approves your surgery, I will continue to see you at least every two months for six months after the surgery. If you fusion is successful (as defined in section VIII-B of the guidelines), I will consider you to be stable and will ask for an impairment rating to complete your care. If you continue to have pain after your surgery and I cannot find a medical reason for it, the department may not continue to pay for your medical care.

By signing this form, we (the *patient* and *physician*), attest that we have discussed the information presented here, we understand this information, and we wish to proceed with the fusion procedure. **We also understand that this information does NOT take the place of, and is separate and distinct from, the surgical consent form that we will review and sign prior to surgery.**

_____	_____
Patient Name	Physician Name
Date: ___/___/___	Date: ___/___/___

***** Gary Franklin, MD, et. al., "Outcomes of Lumbar Fusion in Washington State Workers' Compensation" SPINE 1994, Vol 9, No. 17, pp. 1897 – 1903.

Surgery for Thoracic Outlet Syndrome (TOS)

TYPE OF TOS	SUBJECTIVE		OBJECTIVE		IMAGING
VASCULAR TOS ARTERIAL	At least **three** of the following must be present in the affected upper extremity: A. Pain B. Swelling or heaviness C. Decreased temperature or change in color D. Paresthesias in the ulnar nerve distribution	**AND**	At lease **one** of the following: A. Pallor or coolness B. Gangrene of the digits in advanced cases	**AND**	C. Abnormal arteriogram
VASCULAR TOS VENOUS	At lease **three** of the following must be present in the affected upper extremity: A. Pain B. Swelling or heaviness C. Decreased temperature or change in color D. Paresthesias in the ulnar nerve distribution	**AND**	At least **two** of the following: A. Swelling of the arm, B. Venous engorgement C. Cyanosis	**AND**	D. Abnormal venogram
NEUROGENIC TOS	In the affected upper extremity: A. Pain ***and*** B. Numbness or paresthesia in the ulnar nerve distribution	**AND**	In the affected upper extremity, **all of the** following electrodiagnostic abnormalities must be found: A. Reduced amplitude median motor response ***and*** B. Reduced amplitude ulnar sensory response ***and*** C. Denervation in muscles innervated by lower trunk of the brachial plexus		

*1 The clinical findings in TOS may be similar to those in carpal tunnel syndrome, ulnar neuropathy or cervical radiculopathy. A physician should consider these alternative diagnoses before requesting TOS surgery.

2. Most patients with TOS have cervical ribs.

3. The Department of Labor and Industries has recently concluded a retrospective study of outcomes of thoracic outlet surgery on patients with Labor and Industries claims. The results indicate that long-term outcomes after TOS surgery are worse than outcomes with medical management of TOS.

SEE NEXT PAGE FOR DETAILS OF CRITERIA

Reference: Provider Bulletin 95-04; Date Introduced: April 1995

Criteria For The Electrodiagnostic Diagnosis Of Unilateral Neurogenic Thoracic Outlet Syndrome (TOS)**

All 3 of the following criteria must be found in the affected limb:

1. Amplitude of median motor response is reduced
   And
2. Amplitude of ulnar sensory response is reduced
   And
3. Needle exam shows denervation in muscles innervated by lower trunk of brachial plexus.

Details Regarding the Above Noted Criteria:

Criterion #1

a) Using standard surface electrodes with active pick up over the abductor pollicis brevis, the amplitude of the median motor response on the affected side should be less than 50% of that obtained on the unaffected side.

Criterion #2

a) Using standard ring electrodes on the fifth digit, the ulnar sensory amplitude on the affected side should be less than 60% of the amplitude on the unaffected side.

Criterion #3

a) Muscles innervated by the lower trunk of the brachial plexus include the abductor pollicis brevis, pronator quadratus, flexor pollicis longus, first dorsal interosseous, abductor digiti minimi, flexor carpi ulnaris, extensor pollicis brevis, and extensor indicis.

b) EMG abnormalities in TOS are most commonly seen in median and ulnar innervated intrinsic muscles of the hand -- especially the abductor pollicis brevis.

c) Positive waves and fibrillations may be found, but chronic denervation changes are more common -- that is, increased motor unit amplitude, increased motor unit duration, and decreased recruitment with rapid firing of motor units are activated.

Notes

The electromyographer should rule out neuropathic conditions that might mimic TOS, specifically cervical radiculopathy, carpal tunnel syndrome, ulnar neuropathy and polyneuropathy.

**Abstracted from Wilbourn A.J. American Association of Electromyography and Electrodiagnosis. Case Report #7: True Neurogenic Thoracic Outlet Syndrome. 1992.

Diagnoses and Treatment of Work-Related Carpal Tunnel Syndrome (OCTS)

These guidelines are to be used by physicians and Labor and Industries claim managers.

SECTION 1 -- CLAIM ACCEPTANCE

In general, both appropriate symptoms and signs and work relatedness should be present for Labor and Industries to accept a claim as OCTS. Nerve conduction velocity testing (NCVs) is not necessary for claim acceptance except in questionable circumstances.

A. Symptoms and Signs

Appropriate symptoms would include, numbness, tingling or burning pain of one or both hands, especially noted after work and at night. These nocturnal symptoms are prominent in 50-70% of patients. Patients frequently awaken at night or early morning and shake their hands to rid themselves of these symptoms. The location of these symptoms may be in the entire hand or localized to the thumb and first two or three fingers. If the nerve symptoms are prominent only in the fourth and fifth fingers (ring and little fingers), a different diagnosis (e.g., ulnar neuropathy) should be considered. Although burning pain is often prominent in the hands and palm side of the wrists, an aching pain may radiate (be felt in) to the medial elbow region or more proximally to the shoulder.

Findings on physical examination (signs) are frequently absent or non-specific. Tinel's sign (tapping on the wrist or over the median nerve) and Phelan's signs (forced flexion of the wrist) are frequently described, but by themselves are not specifically diagnostic of OCTS. Their presence merely corroborates the presence of other clear neurologic symptoms.

Other signs are more specific and include decreased sensation to pin or light touch in the palm and first three digits or weakness or atrophy of the muscles of the thenar eminence (especially the abductor pollicis brevis). The presence of the latter signs (but not Tinel's or Phelan's) may suggest more acute or advanced nerve injury and perhaps the need for more aggressive treatment.

In general, symptoms are better when not working and on holidays when the worker has been removed from the workplace exposure. Non-specific symptoms, (e.g., pain without numbness, tingling or burning; "dropping things") should not be considered for the diagnosis of OCTS.

Reference: Provider Bulletin 95-10; Date Introduced: November 1995

B. Work-relatedness

Any activity requiring extensive or continuous use of the hands in work may be an appropriate exposure. In general, one of the following work conditions should be occurring on a regular basis:

1) Repetitive hand use, especially for prolonged periods (e.g., keyboard users), against force (e.g., meat cutters) or with awkward hand positions (e.g., grocery checkers), with repeated wrist flexion, extension or deviation as well as forearm rotation, or with constant firm gripping.

2) The presence of regular, strong vibrations (e.g., jackhammer, chainsaw).

3) Regular or intermittent pressure on the wrist. (Note: acute carpal tunnel syndrome may be associated with acute trauma, i.e., fracture, crush injury of wrist, etc.).

The types of jobs that are most frequently mentioned in the literature or reported in L&I's data include: meat cutting; seafood, fruit, or meat processing or canning; carpentry; roofing; dry walling; boat building; book binding; wood products work; dental hygienist; and intensive word processing. This is not an exhaustive list. It is only meant to be a guide in consideration of work- relatedness. If the history of exposure is unclear, then speaking directly with the employer or claimant, or doing a walk through, to obtain more detailed information on job duties would be critical.

NERVE CONDUCTION TESTING (NCVs)
It is critical to obtain NCV testing in the following situations:

1. The attending physician's diagnosis is OCTS, but the clinical criteria (appropriate neurologic symptoms and/or signs) described above are not met.
2. The patient has been on time-loss for OCTS for more than two weeks and the clinical criteria are met.
3. Carpal tunnel decompression surgery is requested.

Conceptually, validation of the clinical diagnosis of OCTS depends on the finding of sequential slowing of sensory and/or motor fibers of the median nerve across the carpal tunnel.

The most useful nerve conduction tests with their ***(upper limit of) normal cut-points*** are as follows:

Median motor distal latency	4.5 msec (slowing would be longer, i.e., greater than 4.5 msec)
Median sensory distal latency	wrist-digit II (14 cm)=3.5 msec palm-wrist (8 cm)=2.2 msec
Median-ulnar sensory latency difference	finger-wrist difference (14 cm)=0.5 msec palm-wrist difference (8 cm) =0.3 msec

These upper limit cut points are derived from published literature. If the electromyographer performs non-conventional tests for OCTS not listed here, normal values should have been established in that physician's laboratory.

Labs can use their own cut points if they have adequately established their own normal values.

In all cases, and particularly in cases with borderline NCV results, control for skin temperature should be documented. In general, the above referenced values will hold for skin temperature in the range of 30-34 degrees Centigrade. Lower temperatures will be associated with falsely slowed NCV results.

An electromyogram (EMG), or needle examination of the muscles supplied by the median nerve, may be useful in documenting actual nerve damage (axonal loss). This test should be done especially in cases with sensory loss, weakness or muscle atrophy in the median nerve distribution.

TREATMENT

A. Conservative treatment

Conservative management may be helpful and may include:

1) Splinting of the wrist. (May be more useful at night).

2) Anti-inflammatory medication including non-steroidal.

3) Steroid injections - although this form of treatment is favored by some physicians, it may not have long term benefits and may itself cause nerve injury. No more than ***two steroid injections over a three-month period*** will be authorized.

The duration of conservative treatment will primarily depend on whether the patient can remain at work. Most patients will improve when off work, whether or not specific treatment is rendered. In some cases, job modification, along with conservative treatment, may improve symptoms and prevent worsening of OCTS. If job modification is not possible, or if the claimant cannot continue working with conservative treatment, then surgery should be considered as a treatment option.

B. Surgery

Decompression of the transverse carpal ligament is the surgical procedure of choice for OCTS. A second procedure, internal neurolysis, or freeing up of the nerve, is sometimes requested; however, there is no evidence to suggest that this procedure is necessary and, in most cases, requests for this procedure will be denied.

In general, the following criteria should have been met for authorization of surgery to occur:

1. The clinical history should be consistent with OCTS.

2. NCVs should have demonstrated a conduction slowing of the median motor or sensory fibers across the carpal tunnel.

3. A course of conservative management must have been tried.

Most studies suggest that in 60-90% of the post-surgical cases the burning pain associated with OCTS will be alleviated. The patient's ability to return to the same job is not clear. If pain persists or recurs, NCVs can help sort out whether nerve entrapment continues to be a problem.

SPECIAL CASES

Questions may arise in several specific situations that may raise questions about the validity of the claim for OCTS or about the need for surgery.

A. Work-relatedness may not be obvious. Some work exposures do not meet the guidelines for work-relatedness. If there is a question about the job exposure and whether such exposure could cause OCTS, the claim manager should refer the case to the occupational medical consultant by calling (360) 902-5026.

B. Surgery may be requested in those injured workers whose clinical picture and work relatedness is quite clear, but whose NCVs are normal. Most clinicians agree that a minority (<10%) of patients with clinical OCTS may have normal NCVs. Options here may be the following:

    1. Were the most sensitive and specific NCV tests done (e.g., palm-wrist median sensory latency)? If not, request that they be done.

    2. If the NCVs were done after a period of not working, previously abnormal NCVs may have returned to normal. It would be reasonable in these cases to suggest that the claimant return to work for a brief time (a few days to a week) and repeat NCVs while they are still working.

C. If OCTS is not documented by clinical criteria and NCV testing, other clinical problems related to repetitive use (i.e., tendonitis) should be investigated and treated appropriately. It would also be important to rule out other neurologic causes of tingling in the hands. Referral to an appropriate specialist (neurologist, physiatrist) would be prudent in such cases.

D. Carpal tunnel syndrome may also be caused by anything that decreases the cross-sectional area of the carpal tunnel or adds to the volume of the carpal tunnel, resulting in increased pressure on the median nerve. This could occur by distortion of the bones or ligaments by fracture or crush injury of the forearm or hand associated with generalized or chronic swelling (edema).

E. Carpal tunnel syndrome may be associated with other chronic conditions that may cause nerve damage or predispose a nerve to injury from compression. The most common of these conditions is diabetes. The key test here is whether, in spite of the presence of such condition, the symptoms of OCTS can be documented to have begun only after beginning work at the job in question.

F. A predisposing, physiological condition is pregnancy, wherein increased plasma volume increases pressure within the carpal tunnel. In such cases, symptoms universally disappear immediately after birth. If they do not, other etiologies (e.g., work-related, diabetes) should be pursued.

RETURN TO WORK AFTER OCTS SURGERY

The vast majority of persons with work-related OCTS are expected to have dramatic relief of their symptoms after carpal tunnel decompression surgery and should return to their same job. Return to work, with or without job modification, should be tried in most people. If symptoms worsen or reappear after return to work, repeat NCVs will help to sort out if OCTS has recurred, and if surgery successfully removed the pressure on the median nerve (NCVs will improve with successful surgery, although they may not return completely to normal).

Criteria for the Diagnosis and Treatment of Work-Related Carpal Tunnel Syndrome				
PROCEDURE	**CONSERVATIVE CARE**	**Clinical Findings**		
		SUBJECTIVE	**OBJECTIVE**	**DIAGNOSTIC**
DECOMPRESSION OF THE MEDIAN NERVE	- Splinting - Anti-inflammatory medication - Steroid injections* * No more than 2 injections in 3 months NOTE: In the absence of conservative care or with minimal conservative care, a request for surgery can still be considered pending clinical findings.	- Complaints of numbness, tingling or "burning" pain of the hand or thumb and first 2 fingers. Nocturnal symptoms may be prominent NOTE: Pain may radiate to inner elbow or to the shoulder	- Decreased sensation to pin in palm and first 3 digits OR - Weakness or atrophy of the thenar eminence muscles.	- Abnormal nerve conduction studies. Any one abnormality in one of the following*. - Median motor distal latency >4.5 msec - Median sensory distal latency wrist digit II (14 cm) >3.5 msec palm-wrist (8 cm) >2.2 msec - Median-ulnar sensory latency finger-wrist difference >0.5 msec palm-wrist difference >0.3 msec OR - Positive Needle EMG in cases of definite sensory deficit in median nerve distribution or weakness/ atrophy of the thenar muscle NOTE: If test result borderline, may want to repeat after (attempts to) RTW. *NCV must be done with control for skin temperature. Values are true for temperature in range of 30-34 C.
	Nerve conduction studies should be done if worker is off work for > than two weeks or surgery requested.			

SECTION 2 -- NEEDLE ELECTROMYOGRAPHY IN THE DIAGNOSIS OF CARPAL TUNNEL SYNDROME

Needle electromyography has only a limited role in the electrodiagnostic evaluation of carpal tunnel syndrome. It should generally not be done if nerve conduction studies are normal. There are three circumstances in which it would be reasonable to do needle electromyography during an evaluation for carpal tunnel syndrome:

a. Nerve conduction studies are abnormal in a manner indicating carpal tunnel syndrome, and the patient demonstrates wasting or clinical weakness of the thenar muscles.

b. The electromyographer suspects that a neuropathic process other than (or in addition to) carpal tunnel syndrome exists (e.g., diabetes).

c. There is a history of an acute crush injury or other major trauma to the distal upper extremity.

SECTION 3 -- WORKSHEET FOR CARPAL TUNNEL SYNDROME ELECTRODIAGNOSTIC STUDIES

DOCTORS PLEASE NOTE: This worksheet should accompany, BUT NOT REPLACE, the detailed report normally submitted to the department.

1. The purpose of this worksheet is to help medical consultants at L&I interpret electrodiagnostic testing that you do on L&I patients. It is for this reason that the worksheet follows on distal latency. The worksheet should be used only when the main purpose of your study is to evaluate a patient for OCTS.

2. You may have an automated system for reporting electrodiagnostic results. Feel free to send this in. But the department's worksheet should also be filled out and submitted.

3. On the worksheet, sensory distal latency should be measured to response peak and motor distal latency should be measured to response onset.

4. It is not necessary to do all the conduction studies listed on the worksheet. You should do only the studies needed to rule OCTS in or out.

5. It is sometimes necessary to do electrodiagnostic tests other than ones listed on the worksheet. If you do any additional studies bearing on the diagnosis of OCTS, please write them in the blank area below the listed studies.

6. If the inching technique of Kimura is used, only a maximum latency difference between 1 cm segments of 0.5 msec will be accepted as specific enough to corroborate the presence of OCTS.

7. The value of other studies of median nerve function has not been proven. These tests are NOT recommended for the diagnosis of OCTS. The following quotation is taken from a literature review published in Muscle & Nerve, 1993, Vol. 16, p. 1392-1414:

> "Several other variations on median sensory and motor NCS's have been reported to be useful for the evaluation of patients with OCTS. The committee's review of the literature indicated that the value of these tests for the clinical electrodiagnostic evaluation of patients with OCTS remains to be established. These electrodiagnostic studies include the following: (1) studies of the median motor distal latency recorded from the lumbrical muscles,.. (2) measurement of the refractory period of the median nerve,.. (3) median motor residual latency measurements,.. (4) terminal latency ratio,.. (5) median F-wave abnormalities,.. (6) median motor nerve conduction amplitude comparisons with stimulation above and below the carpal ligament,.. (7) anterior interosseous/median nerve latency ratio,.. (8) change in median motor response configuration with median nerve stimulation at the wrist and elbow in the presence of Martin-Gruber anastomosis,.. (9) sensory amplitude measurements,.. and (10) measurement of median sensory and motor nerve conduction across the wrist before and after prolonged wrist flexion."

The Washington State Medical Association (WSMA) Medical Treatment Guidelines Subcommittee and the Department of Labor and Industries Office of the Medical Director endorses the opinions in the above quote and believes that electromyographers should act in accordance with these opinions.

Worksheet for Carpal Tunnel Nerve Conduction Studies

	Abnormal cut-point	Right Arm Distal Latency (msec)	Left Arm Distal Latency (msec)
1. Median motor to APB	>4.5 msec		
2. Median sensory over 14 cm (wrist to digit 2 or 3)	>3.5 msec		
3. Median sensory over 8 cm (transcarpal)	>2.2 msec		
4. Median sensory to Digit 4 MINUS Ulnar sensory to Digit 4	>.5 msec		
5. Median sensory (transcarpal) MINUS Ulnar sensory (transcarpal)	>.3 msec		
6. Ulnar sensory to Digit 5	>3.6 msec		

Claim Number: _____

Claimant Name: _____

Additional Comments:

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_____ _____
Signed Date

TO: **Psychiatrists and Psychologists**

FROM: Washington State Medical Association Medical Treatment Guidelines Subcommittee of the WSMA Industrial Insurance & Rehabilitation Committee

and

The Department of Labor and Industries Office of the Medical Director

DATE: November 1, 1995

SUBJECT: ***Guidelines for Psychiatric and Psychological Evaluation of Injured or Chronically Disabled Workers*****

Enclosed you will find a set of suggestions for conducting psychiatric or psychological evaluations of injured workers with chronic pain problems. The suggestions focus on the clinical interview. They identify issues to explore and describe difficulties that frequently arise in evaluating injured workers.

The suggestions were developed for the specific problem of assessing low back pain patients being considered for spinal fusion. Psychological or psychiatric evaluation is required in this setting; that is, *the Department of Labor and Industries does not authorize a lumbar spinal fusion unless the patient has undergone a psychological or psychiatric evaluation*. The WSMA Medical Treatment Guidelines Subcommittee believes that although the suggestions were developed in a very specific context, they could help psychiatrists or psychologists perform elective evaluations of injured workers with a wide range of problems.

The suggestions are being sent to all psychiatrists and psychologists who are Labor and Industries' providers. We hope you will find them useful. Feel free to incorporate the suggestions you find useful into future psychological/psychiatric evaluations.

***** *These guidelines were developed by Labor and Industries in collaboration with the WSMA Medical Treatment Guidelines Subcommittee of the WSMA Industrial Insurance and Rehabilitation Committee.*

Guidelines for Psychiatric and Psychological Evaluation Of Injured or Chronically Disabled Workers

GENERAL

A psychiatric interview can seem threatening to injured workers. They may fear they were sent for evaluation because their doctors or claim managers suspect their conditions are "made up" or "all in their head." Some perceive their industrial claim as a struggle and enter the examination expecting to be discounted. Despite these difficulties, a respectful, patient, and empathic interviewer can learn a great deal. Patients with chronic disability are often in crisis and may be eager to relate their histories if we respond favorably to initial fear and defensiveness.

The purpose of the evaluation may vary, but commonly there are two issues you will be asked to address:

- Is a psychiatric condition present? Responding to this question involves a diagnosis centered assessment compatible with DSM-IV.

- Are there emotional factors that perpetuate physical complaints? These factors may be disorders on Axis I or Axis II, or may be subtle features that by themselves would not result in a psychiatric diagnosis. Subtle factors include unspoken fears, hidden motives, or family dysfunction. This is the more difficult part of the examination, for which experience with chronic disability is helpful. Psychiatric features that commonly contribute to chronic disability include agoraphobia, antisocial and dependent personality traits, perception of harassment at work, and threatened abandonment. Often the dynamic involves a central emotional vulnerability concealed by a screen of disability and physical complaints. To arrive at an understanding of the underlying issue, we will need heightened sensitivity to common patterns in chronic disability. This report provides some suggestions for those who wish to understand these issues.

The Clinical Interview Using DSM-IV published by the American Psychiatric Association describes two interview styles: symptom-oriented or descriptive and insight-oriented or psychodynamic. A symptom-oriented style searches for characteristic signs and symptoms of disorders in DSM-IV and is useful approaching the first question. The second is non-directive and allows examination of unconscious communication. Aspects of both styles are useful in the interview of injured workers.

Reference: Date Introduced: November 1995

As with the insight-oriented style, the interviewer should avoid leading questions. If the person is suggestible or dramatizes illness, questions that infer diagnostic criteria yield positive responses in many categories. For example, with depression, it is better to ask if there has been a change in energy, rather than if energy is low.

Consistent with the symptom-oriented style, it is helpful to provide structure at appropriate times during the interview. Allowing the patient to relate history without direction, though sometimes desirable in psychotherapy, can result in a shallow, uninformed report. It is important to explore symptoms thoroughly in a non-leading way, rather than accept complaints at face value. To become aware of hidden fears or motives, the interviewer must sometimes actively pursue clues from the interview or the file.

Medical Records

Another area of importance is review of medical records. Records from before the injury can be particularly important. As you review medical records be alert for several features. First, be aware of "functional findings" or signs that are inconsistent with organic illness, as described below. Second, assess attitude toward treatment and the medical and vocational system. If there is a recurrent pattern of passive resistance to all forms of treatment, there is reason to suspect psychological factors contribute to the disability. Third, look for evidence of substance abuse.

Functional findings include:

- Waddell's criteria for assessment of low back pain:
  a) Diffuse tenderness, especially to light touch.
  b) Inconsistent direct versus indirect observation, such as discrepancy of straight leg raising, sitting and supine.
  c) Pain on truncal rotation.
  d) Pain on axial compression.
  e) An abnormal degree of verbal or nonverbal pain behavior such as wincing, groaning, dramatic limp, or dramatic tearfulness during physical examination.

- Non-anatomic sensory disturbance, such as glove or stocking hypalgesia.

- Give-way weakness.

If there are inconsistencies comparing history with information from the medical file, it may be informative to ask about the inconsistencies.

GUIDELINES

Confidentiality

Generally, the interview is not a dyad. There are other interested parties, and it is necessary to explain that information is not confidential. Because of this public framework, it can facilitate communication if you dictate the report during the interview.
The person is then aware what other parties will hear and may feel reassured if the report is accurate and empathic. Also, allowing correction of potential errors may further a sense of control and enhance disclosure.

Introduction

Introduce yourself and explain the circumstances of the interview. Explain who will have access to the report. Personal information will be asked about, but the person can freely choose not to respond if uncomfortable with doing so. If true, it may be helpful to explain that psychiatric assessment is commonly requested when a physical injury has become chronic or when complex surgery is being considered, and the request for evaluation does not necessarily infer anything more than that.

The report should identify age, race, date and nature of injury, and any specific concerns about the evaluation.

Chief Complaint

Obtain a list of symptoms and complaints, including physical problems.

Circumstances Prior to the Injury

A traditional format might collect information regarding present illness at this point. Many use this format with good results. However, clarifying life events that precede the injury affords a broader perspective when the interview progresses to present illness. In either case, the following points should be covered at some point in the interview.

- Employment:

  Security of employment: If recently employed, or if the nature of work is intermittent, ask the percentage of time employed over last few years, and the reason for periods of unemployment. Ask the reason for leaving earlier employment. Assess changes in the economy for the industry, for example, whether the company is still in business or whether layoffs were planned.

  Employment problems: This area is often fruitful, and should be carefully examined. Determine what the supervisors were like to work for, and if there was harassment or conflict with coworkers or supervisors. Determine how the person's work performance was viewed by superiors, and if reprimands or complaints were filed by

the person or the employer. Carefully assess for perceptions of harassment or discrimination.

Employment plans: Ask about career plans before the injury.

- Family relationships:

  Spouse: Ask age, health, and employment status of spouse, as well as length of relationship. Is the spouse disabled? How do they get along? Were they ever separated? If this (or any important relationship) was threatened, try to determine if disability might be a conscious or unconscious tool for stabilizing the relationship.

  Children: Ask ages, health status, who is at home, and if there have been any significant problems.

  Other Family: Ask about any other family with frequent contact. It is useful to know if there has been recurrent conflict or any major losses in the family.

- Activities: Ask how leisure time is spent, hobbies, avocational interests. Ask how the injury has affected pleasurable activities.

- Interpersonal Relationships: Assess patterns of isolation Vs socialization. Ask about friends, comfort in group situations, as well as comfort being alone. Is there capacity for intimacy and for communication of personal concerns?

History of the Injury

A thorough history of how the injury occurred can be informative, especially if it may have been emotionally traumatic or head injury is suspected. If the injury was traumatic, determine if PTSD symptoms are present. A non-leading way might be to ask if much time is spent thinking about the accident and how it feels to think about it. It is also important to know if there is anger, blame, or guilt regarding circumstances of the injury.

Elicit a history of important events subsequent to the accident, including medical treatment and effects on family, work and finances. Bankruptcy, eviction, foreclosure, or repossession can contribute to chronic disability.

Medical History

The report should include a brief history of treatment and response, with a focus on:

- Medical system: The relationship with doctors, vocational counselors, and others is an important clue to personality function and motivation. If there is a pervasive pattern of being misunderstood and persecuted you might suspect character

pathology is a block to recovery. Unrealistic blame, martyrdom and entitlement suggest a hidden desire to remain disabled.

- Results of Treatment: Determine the longitudinal course of the illness. Individuals with chronic disability usually report that no treatment has provided lasting benefit, and the illness has steadily worsened despite all treatment efforts. What you may discover in talking with individuals with chronic disability is a curious contradiction between verbal and other channels of communication. On the surface, there is a positive image of a strong desire to recover and return to work, but upon wading into this stream one becomes aware of a strong undercurrent in a different direction. This is difficult to describe, but often it appears as a discomfort with certain topics and a pattern of communicating through inference. For example, the desire for recovery is vague, lacking a specific plan beyond continuation of passive treatments. Persistence in asking about plans may lead to irritability. They often mention the opinions of others, usually health care professionals, who think they are disabled. If you ask for specific information hoping to better understand a particular symptom, you might receive instead an illustration of how severely life has been affected by the symptom. They imply inability to function unless the illness resolves. They may seem preoccupied with additional treatment, particularly surgery or other passive approaches, and demonstrate resistance to physical conditioning and work hardening. They may be critical of prior physicians who expected too high a level of functioning and seem more comfortable with doctors willing to validate disability indefinitely.

  A way to open this area of inquiry might be to ask what the person believes is the cause of the problem, and if they feel doctors have addressed the problem. Ask what they would like to see happen.

- Locus of Control: Is the person's role passive, waiting for others to restore function, or is the injury a personal setback that must be adjusted to.

Work Since the Injury

Obtain a chronological history of work since the injury, including the reason for any disruptions. How was the person welcomed upon return? Blame for the injury, demotion, or suspicions of malingering are very stressful and can contribute to chronic disability. Conversely, acceptance and patience aid recovery. Ask about employment plans. If the person does not feel able to work, determine which symptoms present a barrier. Ask if the employer is receptive, or if the person has looked for work, and if so, the result. What level of income/status is acceptable? What does the person envision two years from now?

Psychiatric History

In addition to a general assessment of psychiatric symptoms, determine how life has been affected by the injury and how the person has adjusted to the changes. Generally, it is best to allow an unstructured recitation of events since the injury.

Common psychiatric findings are depression and panic disorder.

For depression, ask how the person's mood or spirits have been. If there is depression, what seemed to be the precipitant? Obtain a description of what it was like at the lowest point. If there is evidence for mood disorder, develop a history of any diagnostic criteria. It is important to distinguish effects of pain. For example, if there is middle insomnia, were the awakenings spontaneous (consistent with major depression) or due to pain. What did the person do upon awakening? Getting up to walk and relieve stiffness or pain suggests awakening due to pain.

Similar differential inquiries are necessary for disturbances of appetite, energy, libido, and ability to experience pleasure.

Panic disorder is common enough in the general population, but it is very common in the population described by chronic disability. When panic attacks occur in individuals who have trouble expressing emotion or who feel shame regarding emotional symptoms, the presentation is likely to be one of pain rather than anxiety. Discovering the condition, however, can be difficult.

The most sensitive screening seems to be a careful assessment of current activities, which is also useful. Avoidance of the typical problem areas for agoraphobics such as grocery stores, shopping malls, crowds and driving raises the suspicion of agoraphobia. From there you might ask how the person feels in these situations, and what happens that creates discomfort. Additionally, you may ask if there have been any spells involving dizziness or heart or breathing symptoms. If screening questions are positive, develop a full DSM-IV history, especially for agoraphobia. If panic attacks were present, what did the person do or feel like doing when they occurred at work.

Narcotic and alcohol dependence are often found in chronic disability. It is often difficult to assess this issue without information from the medical file.

Current Activities

Ask how time is spent. Boredom, purposelessness, or severe physical limitations may lead to depression.

Secondary gain from the family should be assessed. It is useful to know how the family has responded, for example if they have been supportive or impatient. What are the responsibilities at home? Have family members become employed as a result of the injury, or alternatively, have family members sacrificed employment or other activities to care for the person?

Past Psychiatric History

Ask about prior illness, carefully assessing for substance abuse; use of psychiatric medication; evidence of sociopathy such as arrests; and history of prior trauma such as combat that might lead to PTSD. Assess carefully for substance abuse, relying on potential clues from medical records as well as the clinical history.

Past Medical History

Determine response to any prior illnesses or injuries. Important clues may come from medical records. Determine whether there were long periods of disability. Ask about the emotional response to prior injuries.

Family History

In addition to asking about familial illnesses such as mood disorders, substance abuse, and anxiety disorders, determine whether family members have been disabled.

Personal History

The record should include a customary history of the person's life, with emphasis on factors that have bearing on chronic disability. Such factors include:

- Family structure: A childhood history of conflict, abuse, or deprivation correlates with chronic disability. Determine the number and health of siblings and whether the parents stayed together. Obtain a history of adults in the home. Ask if they have worked steadily. Ask about their health, listening carefully for history of chronic illness, agoraphobia, depression, hypochondriasis, somatization, illness of the same kind the patient experiences, or periods of disability.

  Ask about the relationship with adults, following affect carefully for cues. Helpful questions might include, "What was he [or she] like when you were a child?" "How did he relate with you?" "Did you feel loved?" It is important to determine if sexual, physical or verbal abuse, or episodes of abandonment were present. Determine if alcohol or drug abuse was present in parents. Are childhood memories contiguous? Was there acting out, which might suggest deprivation or abuse?

  If there are risk factors for abuse, ask about symptoms of PTSD such as dissociation, nightmares, and flashbacks. History of abandonment, neglect, and parental indifference are important.

- Education: Ask for education level, grade point, any special education, honors, repeating or skipping classes. Learning disabilities, attention deficit disorder, or educational failures can contribute to shame and a perception of low worth in the job

market, which can fuel chronic disability. If there seems to be a disparity between educational and occupational success, try to discover the reason.

- Marital history: Look for clues suggesting difficulty sustaining relationships or antisocial traits.

- Employment history: A history of menial, unrewarding, or excessively demanding work correlates with chronic disability. Vocational difficulty may be indicated by frequent job change, being fired, and aimlessness.

Mental Status Examination

As in a standard mental status examination, report general appearance, attitude, motor behavior, speech pattern, affective state, thought processes, perception, intellectual function, orientation, memory and judgment. In addition, describe pain behavior and genuineness.

Describe any personality traits which may influence chronic disability, such as:

- Lack of empathy or self-absorption, as in attitudes of entitlement or antisocial indifference.

- Alexithymia and globally deficient insight with rigid, irritable avoidance of emotion.

- Evasiveness and discomfort with specific questions. Emphasis on an "industrial" explanation for symptoms with minimization of other stressors.

- Repeatedly seeing oneself as a victim.

- Chronic anger, projection of blame, or passive-aggressive patterns of response.

- Dependent traits, such as submissiveness, undue anticipation of others' needs, impaired assertiveness, and excessive longing to feel loved.

- Histrionic traits, psychological naiveté, and Pollyanna attitudes.

DSM-IV Diagnoses

Specify Axis I, II, IV and V, with findings that lead to each diagnosis.

Conclusions

In addition to responding to referral questions, it is useful to include:

- Risk factors for chronic disability and barriers to recovery. Identify which barriers may be treatable and which will probably not be responsive.

- An assessment of psychological factors in this person's presentation of illness. Explain as clearly as possible how, if at all, the emotional condition may contribute to disability.

- Treatment recommendations. Treatment for psychiatric illness due to the injury might be indicated. If treatment is recommended, you may wish to make specific recommendations for the attending orthopedist or neurologist to consider. If treatment is recommended, try to estimate prognosis and a time-frame.

- Alternatively, the history might reveal psychological features that are primarily responsible for the disability. In that case, it may be necessary to assist in setting limits on medical services and disability status.

- Ability to Work. Some patients will have a psychiatric disorder that limits or prevents employment. Others will have a psychiatric condition that interferes with comfort or willingness, but ability to work is not affected. It is important to differentiate impaired motivation from impaired ability to work, and to communicate the difference in the report.

Collaborative Guidelines On The Diagnosis Of Porphyria And Related Conditions

Prepared By

The Washington State Department of Labor and Industries
And
The Washington State Medical Association's
Committee On Industrial Insurance And Rehabilitation

October 18, 1995

Purpose and Development of these Guidelines

The purpose of these guidelines is to provide information for treating physicians and independent medical examiners to use in evaluating patients with possible exposure-related porphyria, and to provide a foundation for developing Department medical policy.

The focus of these guidelines is on the phase of the medical evaluation where a decision must be made whether to proceed with an extensive work-up to reach a definitive diagnosis, or to conclude that results of a preliminary evaluation make a diagnosis of porphyria unlikely (see Section III). It is beyond the scope of these guidelines to provide detailed algorithms for reaching a conclusive diagnosis.

These guidelines were developed with the input and approval of numerous nationally and internationally recognized experts on porphyria. Input was also incorporated from many other individuals, including physicians representing a wide variety of specialties and non-physicians with an interest in this topic.

The scientific basis for these guidelines, along with additional information about their development, can be found in a review document on porphyria prepared by the Office of the Medical Director of the Washington State Department of Labor and Industries. These guidelines may be revised as new scientific information becomes available.

Date Introduced: October 1995

General Information

Porphyrias are metabolic disorders in which the clinical manifestations are attributable to decreased activity of a specific enzyme(s) in the heme synthesis pathway, associated with characteristic patterns of overproduction of specific heme precursors and resultant accumulation in certain tissues. Each enzyme deficiency results in a predictable accumulation of the preceding heme precursor(s), and overall production of heme is generally preserved. Porphyrias, when clinically active, and in some cases even when latent or in clinical remission, are characterized by high levels of heme precursors in blood, urine, and/or stool. Most types of porphyria are inherited conditions; however, one type of porphyria, porphyria cutanea tarda, is known to occur in acquired or inherited manner.

Many of the tests used to diagnose the porphyrias are nonspecific and are abnormal in many circumstances other than the porphyrias. Porphyrinuria, i.e., increased urine porphyrins, can be caused by porphyrias, by a number of other medical conditions, and by a variety of exogenous factors such as alcohol and certain drugs and chemicals that disturb heme synthesis or stress heme-dependent metabolism. The term "secondary porphyrinuria" is commonly used in reference to the porphyrinuria occurring with conditions and factors lacking a primary enzyme defect in heme synthesis. It usually involves mild or moderate coproporphyrinuria, with no or little excess uroporphyrin in urine, and is also often called "coproporphyrinuria" or "secondary coproporphyrinuria."

In individuals who are genetically predisposed to developing an acute or cutaneous porphyria, manifestations of porphyria can be *triggered* by a variety of exogenous factors including alcohol, certain therapeutic drugs and chemicals, infections, dietary factors and sun exposure, as well as by certain medical conditions and endogenous factors such as menstruation and administered steroid hormones. Exogenous factors can also *cause* changes in the heme synthesis pathway, even in the absence of genetic predisposition; in some cases, these acquired changes have been reported to cause porphyria cutanea tarda.

Lead absorption, both acute and chronic, is well documented to affect heme synthesis. Lead causes accumulation of protoporphyrin in erythrocytes and large increases of ALA and coproporphyrin in urine. Lead inhibits ALA dehydratase, and also appears to interfere with the function of two other heme synthesis enzymes. Lead intoxication is generally classified as a secondary porphyrinuria rather than as an acquired porphyria, although it does have clinical and biochemical similarities with acute porphyrias.

A number of chemicals, primarily halogenated hydrocarbons and metals, are known to be "porphyrogenic" (i.e., capable of inducing changes in heme synthesis, with subsequent overproduction and excessive excretion of heme precursors) in experimental animals, generally with doses much greater than the range of human experience. In humans, with the noteworthy exceptions of porphyria caused by hexachlorobenzene and the "porphyrinuria" caused by lead, reports of porphyria or porphyrinuria attributable to chemical exposures have been infrequent. It must be acknowledged, however, that there has been only limited systematic study of the subject in humans. The reported

findings have generally been linked to chronic industrial exposures, industrial accidents, or environmental exposures that were much higher than normally encountered.

Diagnosis

The most important first step toward diagnosing or ruling out porphyria in a symptomatic patient is for the physician to maintain a high index of suspicion for a possible diagnosis of porphyria, whether symptoms are "classic" for a porphyria or are vague or unexplained. The conclusive diagnosis of a porphyria should be based on a systematic approach incorporating medical history, physical examination, and biochemical data, including genetic evaluation if necessary. Certain symptom patterns, physical findings, and elements of the exposure history may raise the degree of suspicion for porphyria; however, the lack of supporting information from these sources cannot exclude a diagnosis of porphyria. Therefore, the systematic approach to evaluating a symptomatic patient with suspected porphyria should begin with laboratory evaluation.

In a person with symptoms from a porphyria, the level of the most excessively excreted heme precursor is typically at least several-fold greater than the upper limit of values found in normal individuals.

A. Minimum ("Threshold") Criteria

Physicians must sometimes decide whether an extensive work-up for porphyria is indicated. In order to assist clinicians in this decision, the following threshold criteria are recommended:

In a patient who is currently or recently symptomatic and who is suspected to have a porphyria, it is not probable that the patient's symptoms are attributable to a porphyria of any type unless a measurement on at least one of the following tests is greater than twice the upper limit of normal:

- **urine porphobilinogen (PBG)**
- **urine uroporphyrin**
- **urine coproporphyrin**
- **fecal coproporphyrin**
- **blood total porphyrins**

B. Caveats

1. **Reference range:** Because a reference range may be unique to the assay method and the individual laboratory performing the test, test results should be interpreted relative to the laboratory-specific reference range and/or, if sufficient general clinical experience exists, against accepted absolute reference standards.

2. **Blood Lead Level:** A blood lead level should be checked to determine the possibility of lead intoxication if lead exposure is suspected, if excretion of coproporphyrin or ALA is increased, or if blood porphyrins (e.g., blood zinc protoporphyrin [ZPP]) are increased.

3. **Repeat testing and factors affecting test results:** Laboratory test results, in general, can be compromised by a variety of factors including specimen integrity, analytical quality, limitations of analytical methods, and the applicability and specificity of reference ranges or "control" data. Issues of specimen integrity may be particularly relevant when specimens are collected and processed at one site, and then transported to a geographically distant reference laboratory.

   Because of these risks, an abnormal test result generally should be confirmed by analysis of a second specimen before the test result is used to finalize a diagnostic conclusion. The need to repeat a test, of course, must be tempered by the degree of support for a diagnosis from other clinical and laboratory data, and by the feasibility of repeating the test (i.e., the appropriate clinical circumstances should still be present).

4. **Enzyme measurements:** If a person is currently or recently symptomatic and is found to have reduced activity of a specific heme synthesis enzyme, but laboratory testing does not also reveal overproduction and excessive excretion of heme precursors in a pattern and levels consistent with the porphyria specific to that enzyme, then the reduction in measured enzyme activity has no probable causative relationship to the person's symptoms.

5. **Additional testing:** Satisfaction of these "twice the upper limit of normal" criteria *does not necessarily establish* a diagnosis of porphyria. Depending on the degree and pattern of abnormalities on these tests, additional testing may be necessary to establish or exclude a diagnosis of porphyria. It is possible that an individual could have an abnormal heme precursor measurement with this degree of abnormality (i.e., twice upper normal) as a consequence of something other than porphyria (or lead intoxication). Other medical conditions can cause "secondary" porphyrinuria of this magnitude. Blood porphyrins can also be increased by this magnitude in conditions other than porphyria: for example, iron deficiency commonly produces an increase in blood zinc protoporphyrin (ZPP).

6. **Timing of specimen collection:** Conversely, failure to satisfy these "twice the upper limit of normal" criteria *does not necessarily exclude* a diagnosis of porphyria. Heme precursor measurements in the range of one to two times the upper normal value should not be interpreted as "normal," but rather as *indeterminate or non-diagnostic*. When a patient with suspected porphyria is not currently or recently symptomatic, the levels of heme precursor excretion are generally lower and can even normalize with time. If a patient's last symptoms occurred remotely in time relative to specimen collection, it may be necessary to repeat the tests during or as soon as possible after future symptoms.

7. **"Secondary porphyrinuria":** Porphyrinuria sometimes secondarily reflects the presence of a medical condition or exogenous factor that disturbs heme synthesis or stresses heme-dependent metabolism but produces symptoms through a separate mechanism. With the noteworthy exception of lead poisoning, the porphyrin excess in "secondary porphyrinuria" has no recognized, clinically detectable consequences of its own; symptoms associated with secondary porphyrinuria (other than lead poisoning) are attributed by most experts to the condition or agent causing the porphyrinuria, or to an unrelated cause, and not to a disturbance in heme synthesis. Although the porphyrinuria itself may be benign, the associated medical condition may be far from benign.

   Medical conditions that appear to have only secondary effects on the heme synthesis pathway are appropriately evaluated with attention focused on the primary condition. Similarly, when chemical exposures are suspected as the cause of a patient's symptoms or medical condition, the exposure relationship can be characterized more specifically by assessment of the exposure situation or by quantification of the suspected chemical (or its metabolite) in blood or urine, than by measurement of heme precursors.

Complex Regional Pain Syndrome (CRPS)

Formerly known as Reflex Sympathetic Dystrophy

1. INTRODUCTION

This bulletin outlines the Department of Labor and Industries' guidelines for diagnosing and treating Complex Regional Pain Syndrome (CRPS) – formerly known as Reflex Sympathetic Dystrophy (RSD). This guideline was developed through collaboration between the Washington State Medical Association (WSMA) Industrial Insurance/Rehabilitation Committee and the Office of the Medical Director of the Department of Labor and Industries. The protocol for CRPS physical therapy/occupational therapy (see Table 2) was developed in collaboration with the Washington State Physical Therapy and Occupational Therapy Associations.

2. WHAT IS COMPLEX REGIONAL PAIN SYNDROME?

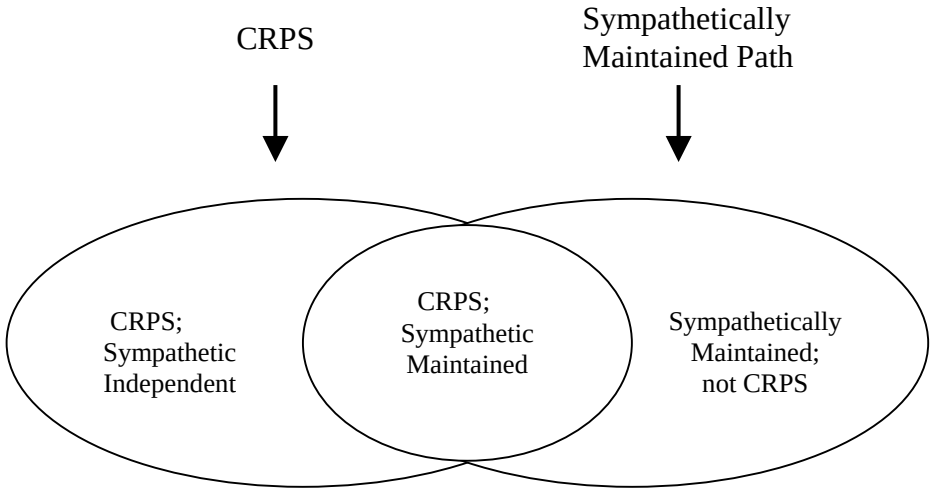
Complex Regional Pain Syndromes are painful conditions that usually affect the distal part of an upper or lower extremity and are associated with characteristic clinical phenomena as described in Table 1. There are two subtypes – CRPS Type I and CRPS Type II.

The term "Complex Regional Pain Syndrome" was introduced to replace the terms "reflex sympathetic dystrophy." CRPS Type I used to be called reflex sympathetic dystrophy. CRPS Type II used to be called causalgia. The terminology was changed because the pathophysiology of CRPS is not known with certainty. It was determined that a descriptive term such as CRPS was preferable to "reflex sympathetic dystrophy" which carries with it the assumption that the sympathetic nervous system is important in the pathophysiology of the painful condition.

The terms CRPS Type I and CRPS Type II are meant as descriptors of certain chronic pain syndromes. They do not embody any assumptions about pathophysiology. For the most part the clinical phenomena characteristics of CRPS Type I are the same as seen in CRPS Type II. The central difference between Type I and Type II is that, by definition, Type II occurs following a known peripheral nerve injury, whereas Type I occurs in the absence of any known nerve injury.

Reference: Provider Bulletin 97-05; Date Introduced: June 1997

Pain that can be abolished or greatly reduced by sympathetic blockade (for example, a stellate ganglion block) is called sympathetically maintained pain. Pain that is not affected by sympathetic blockade is called sympathetically independent pain. The pain in some CRPS patients is sympathetically maintained; in others, the pain is sympathetically independent. The relation between CRPS and sympathetically maintained pain can be seen in the following Venn diagram:



**************************PHYSICIANS PLEASE NOTE***************************

If you believe the CRPS condition is related to an *accepted occupational injury*, please provide written documentation of the relationship (on a more probable than not basis) to the original condition. Treatment for CRPS will only be authorized if the relationship to an accepted injury is established.

3. DIAGNOSTIC CODES

After treatment authorization has been obtained from the claim manager, physicians should use billing codes that are designated for reflex sympathetic dystrophy in the International Classification of Diseases (ICD-9CM) to bill. The relevant code numbers are described below:

ICD 9-CM Code	English Description
337.20	Reflex sympathetic dystrophy, unspecified
337.21	Reflex sympathetic dystrophy of the upper limb
337.22	Reflex sympathetic dystrophy of the lower limb
337.29	Reflex sympathetic dystrophy of other specified site

4. KEY ISSUES IN MAKING A DIAGNOSIS

A. CRPS is a Syndrome – See whether your patient's symptoms and signs match those described in Table 1.

B. CRPS is Uncommon - Most patients with widespread pain in an extremity do **NOT** have CRPS. **Avoid the mistake of diagnosing CRPS primarily because a patient has widespread extremity pain that does not fit an obvious anatomic pattern.** In many instances, there is no diagnostic label that adequately describes the patient's clinical findings. It is often more appropriate to describe a patient as having "regional pain of undetermined origin" than to diagnose CRPS.

C. Is CRPS a Disease? – Many clinicians believe that CRPS can best be construed as a "reaction pattern" to injury or to excessive activity restrictions (including immobilization) following injury. From this perspective, CRPS may be a complication of an injury or be iatrogenically induced but it is not an independent disease process.

D. Type I CRPS vs. Type II CRPS – In a patient with clinical findings of CRPS, the distinction between Type I and Type II CRPS depends on the physician's assessment of the nature of the injury underlying the CRPS. In many situations, the distinction is obvious – if CRPS onsets following an ankle sprain or a fracture of the hand, it is Type I CRPS. If CRPS onsets following a gunshot wound that severely injures the median nerve, it is Type II CRPS. In ambiguous situations (for example CRPS in the context of a possible lumbar radiculopathy), the physician should be conservative in diagnosing Type II CRPS. This diagnosis should be made only when there is a known nerve injury with definable loss of sensory and/or motor function.

5. TYPICAL CLINICAL FINDINGS

A diagnostic algorithm that details the following clinical findings is located in Table I at the end of this guideline.

A. History

1. Symptoms develop following injury (usually symptoms begin within 2 months post injury).
2. Onset is in a single extremity
3. Burning pain
4. Hyperalgesia or allodynia (allodynia means pain elicited by stimuli that normally are not painful, i.e., a patient reports severe pain in response to gentle stroking of the skin.)
5. Swelling
6. Asymmetry or instability of temperature or color
7. Asymmetry or instability of sweating

8. Trophic changes of skin, nails, hair

B. Findings by Examination

1. Hyperalgesia or allodynia
2. Edema (if unilateral, and other causes excluded)
3. Vasomotor changes such as asymmetry or instability of temperature/color
4. Sudomotor changes such as excess perspiration in affected extremity
5. Trophic changes such as shiny skin, hair loss, abnormal nail growth
6. Findings suggestive of impaired motor function such as:

(a) tremor
(b) abnormal limb positioning
(c) diffuse weakness that cannot be explained by neuralgic loss or by dysfunction of joints, ligaments, tendons or muscles.

C. Diagnostic Test Results

A three-phase bone scan with characteristic pattern of abnormality. (NOTE – An abnormal bone scan is **not** required for the diagnosis of CRPS.)

D. Lack of Reasonable Alternative

No other anatomic, physiologic or psychological condition that would reasonably account for the patient's pain and dysfunction.

6. SYMPATHETIC BLOCKADE IN THE DIAGNOSIS OF CRPS

A. CRPS is considered a clinical syndrome, based on the criteria previously described in typical clinical findings and detailed in Table 1.

B. A patient's response to a diagnostic sympathetic block provides information about whether his/her pain is sympathetically maintained, but neither establishes nor refutes a diagnosis of CRPS. Therefore, a sympathetic block is not considered to be a definitive diagnostic test for CRPS.

C. In the patient with CRPS the purpose of a sympathetic block is to guide treatment. If a CRPS patient responds positively to a sympathetic block (indicating that his/her pain is sympathetically maintained) repeat blocks might be useful in the overall treatment plan.

D. If a patient does NOT meet the criteria for diagnosing CRPS as given in Table I, but the attending physician feels that the patient has sympathetically maintained pain, you may request authorization for a diagnostic sympathetic block. Requests to the state fund for a diagnostic sympathetic block should be sent to the L&I Office of the Medical Director for review.

7. AN OVERVIEW OF TREATMENT

Experts in CRPS believe the probability of a patient developing this condition can be reduced by early mobilization/activation following injury or surgery. Conversely, unnecessarily prolonged immobilization following injury or surgery may set the stage of iatrogenic CRPS. Therapy for CRPS should be directed toward the goals of physical restoration and pain control. Details regarding treatment are presented in Tables 1 and 2 located at the end of this Guideline.

A. Physical Restoration

Experts agree that CRPS patients usually become trapped in a vicious cycle in which guarding and activity restrictions perpetuate the pain of CRPS. Therapy for CRPS should be directed toward breaking the pain cycle by having patients participate in a progressive activation program for the affected limb.

1. Because patients usually resist using the affected extremity, the physical restoration program generally requires supervision by a physical therapist or occupational therapist.
2. Involvement of a physical or occupational therapist is important so that repeated measurements of a patient's functional capacity can be made.
3. The frequency with which a patient receives physical or occupational therapy must be individualized by the attending physician.
4. Physical or occupational therapy occasionally continues beyond the time period during which pain control interventions such as sympathetic blocks are administered. Such prolonged therapy will be authorized as long as there is evidence of ongoing improvement of function of the limb.
5. Patients need to understand they must use their symptomatic limb in the course of their usual daily activities as well as during physical or occupational therapy sessions. Patients must commit themselves to physical restoration on a 24-hour per day basis.

B. Pain Control

1. Interventions to reduce pain are typically needed so that patients can get enough relief to participate in an activation program.
2. It is crucial that pain control interventions be linked closely with physical/occupational therapy. Physical or occupational therapy sessions should be scheduled as soon as possible after a sympathetic block. The interval between block and therapy should always be less than 24-hours. In general, physical/occupational therapy should be directed toward activation and desensitization in the affected limb. Details are given in Table 2.
3. Clinicians use a variety of medications to control pain in patients with CRPS. These include alpha adrenergic blockers, corticosteroids, antidepressants, anti-seizure medications, mexiletine and opiates. The Department of Labor and Industries has no formal guideline regarding a specific medication regimen for CRPS.

C. Sympathetic Blocks

1. In a patient who meets criteria for CRPS, up to 3 sympathetic blocks will be authorized to allow the attending physician to determine whether the patient has sympathetically mediated pain.
2. Additional blocks will be authorized ONLY if there is evidence from the first three that the patient has sympathetically mediated pain.
3. The physician who performs each sympathetic block should document:
   (a) Measurable evidence that a sympathetic blockade in the target limb was achieved – e.g., hand/foot temperature before and after the block, observed color changes and/or venodilation.
   (b) The extent and duration of the patient's pain relief, based on a pain diary.

4. A patient should be seen by a physical or occupational therapist during the time interval when a sympathetic block would be expected to have an effect – that is, within a few hours of the block. The therapist should document the functional status of the patient's symptomatic limb during the therapy session.
5. The attending physician or the physician performing sympathetic blocks should correlate the information previously described n #3 and #4 to determine whether a block has produced the intended effects on pain, function and observable manifestations of CRPS.

D. Psychological Treatment

The clinical course of many patients with chronic pain, such as those with CRPS, may be complicated by pre-existing or concurrent psychological or psychosocial issues. A one time psychological/psychiatric consultation may be requested to assist in the evaluation of such patients.

For those patients you feel require treatment for psychological/psychiatric disorders, authorization for such treatment will be considered only under the following conditions:

The psychological/psychiatric consultation has led to a psychiatric diagnosis (that is, a DSM4 diagnosis),

AND 1) **EITHER** the diagnosed psychiatric condition must be considered causally related to the industrial injury,

2) **OR** the diagnosed condition must be retarding recovery from the industrial injury.

E. Treatment Phases

Treatment is divided into six-week phases. A maximum of three phases may be authorized. The second phase will be authorized only if the first phase has led to demonstrable functional improvement. The third phase may be authorized only if the first and second phases have led to demonstrable functional improvement.

1. In the first six-week phase, up to 5 sympathetic blocks will be authorized (along with other accepted conservative measures such as medication management).
2. During the second six-week phase, a total of 3 sympathetic blocks will be authorized.

3. Up to 3 more sympathetic blocks may be authorized for patients who go on to the third phase of treatment.

F. Hospitalization

Hospitalization is rarely appropriate in the treatment of CRPS. The only exception to this is that a CRPS patient might have an orthopedic condition that is amenable to surgery. Because CRPS patients are at high risk for flares after surgery, it is reasonable for such a patient to be admitted to a hospital prior to surgery so that aggressive pain control measures may be undertaken preoperatively.

G. Sympathectomy

Sympathectomies are not indicated for CRPS and are NOT COVERED.

8. REFERENCES

1. Janig W & Stanton-Hicks M (ed) Reflex Sympathetic Dystrophy: A Reappraisal. Seattle: IASP Press, 1996.
2. Merskey H & Bogdud N (ed) Classification of Chronic Pain (2nd ed). Seattle: IASP Press 1994.

Table 1
Labor And Industries
Criteria Number 13
Chronic Regional Pain Syndrome (CRPS)
Conservative Treatment Guideline

EXAMINATION FINDINGS & DIAGNOSTIC TEST RESULTS	**CONSERVATIVE CARE**
At least **four** of the following **must be present** in order for a diagnosis of CRPS to be made. ***EXAMINATION FINDINGS:*** 1. Temperature/color change 2. Edema 3. Trophic skin, hair, nail growth abnormalities 4. Impaired motor function 5. Hyperpathia/allodynia 6. Sudomotor changes ***DIAGNOSTIC TEST RESULTS*** 7. Three-phase bone scan that is abnormal in pattern characteristics for CRPS. This test is not needed if 4 or more of the above examination findings are present. **SURGICAL INTERVENTION (SYMPATHETECTOMY) FOR TREATMENT OF THIS CONDITION IS NOT COVERED**	Early aggressive care is encouraged. Emphasis should be on improved functioning of the symptomatic limb. **FIRST SIX WEEKS OF CARE:** - Sympathetic blocks, maximum of **five**. Each block should be followed immediately by physical/occupational therapy. - Physical/occupational therapy should be focused on increasing functional level (see Table 2). - Other treatment, e.g., medication at MD's discretion as long as it promotes improved function. ***AFTER THE 1ST SIX WEEKS OF CARE:*** - Strongly consider psychiatric or psychological consultation if disability has extended beyond 3 months. - Continued physical/ occupational therapy based on documented progress towards goals established during first 6 weeks (referenced above). - Sympathetic blocks only if response to previous blocks has been positive, maximum of 3** every six weeks for a maximum of 12 weeks. ****A maximum of 11 blocks can be delivered over the total 18 week period.**

Table 2

Labor And Industries
Criteria Number 13
Chronic Regional Pain Syndrome (CRPS)
Conservative Treatment Guideline

PROTOCOL FOR PHYSICAL THERAPY/OCCUPATIONAL THERAPY FOR CRPS

1. Evaluation should:
- **A.** Include a date of onset of original injury (helpful in determining if early or late stage) and a date of onset of the CRPS symptoms.
- **B.** Establish a baseline for strength and motion.
- **C.** Establish a baseline for weight bearing for lower extremity.
- **D.** If lower extremity, evaluate distance able to walk and need for assistive device.
- **E.** If upper extremity, establish a baseline for grip strength, pinch strength and shoulder range of motion.
- **F.** If possible, objectify swelling (e.g., do volume displacements).
- **G.** Define functional limitations.

2. Set specific functional goals for treatment related to affected extremity.

3. All treatment programs should include a core of:
- **A.** A progressive active exercise program, including a monitored home exercise program.
- **B.** Progressive weight bearing for the lower extremity (if involved).
- **C.** Progressive improvement of grip strength, pinch strength and shoulder range of motion of the upper extremity (if involved).
- **D.** A desensitization program.

4. For specific cases, additional treatment options may be indicated to enhance effectiveness of the above core elements. Documentation should reflect reasons for these additional treatment options.

5. Documentation should include:
- **A.** At least every two weeks, assessment of progress towards goals.
- **B.** Response to treatment used in addition to core elements (listed above in section 3).
- **C.** Evidence of motivation and participation in home exercise program, i.e., diary or quota system.

Fibromyalgia

Purpose

Fibromyalgia is a complex pain disorder that raises many questions for providers, particularly as to whether this condition is related to the industrial insurance system. The purpose of this bulletin is to answer a few of those questions:

- Is fibromyalgia accepted as an industrial injury or occupational disease?
- If a provider asserts a worker's fibromyalgia is related to the industrial injury or occupational exposure, what type of documentation should be submitted to support this contention?
- Will the department or self-insurer pay for short-term treatment of fibromyalgia?

Is fibromyalgia accepted as an industrial injury or occupational disease?

The Office of the Medical Director at the Department of Labor & Industries, in collaboration with the Washington State Medical Association's Industrial Insurance Guideline Subcommittee, studied fibromyalgia and the medical literature that addresses the causes of fibromyalgia. After careful consideration, it was determined that there is not sufficient medical data at this time to establish a causal relationship between an industrial injury or occupational exposure and the subsequent development of fibromyalgia.

Based on this lack of scientific evidence, the department does not generally recognize fibromyalgia as an industrial injury, an occupational disease, or an aggravation to a pre-existing condition.

The worker's health care provider may submit additional information, as described below, that the provider believes rebuts, or challenges, this general policy for an individual worker.

Reference: Provider Bulletin 98–11; Date Introduced: November 1998

If a provider asserts a worker's fibromyalgia is related to the industrial injury or occupational exposure, what type of documentation should be submitted to support this contention?

A provider who feels that a worker's fibromyalgia is causally related to an industrial injury or occupational disease is encouraged to submit additional information to support that diagnosis. The kinds of information useful in this regard include:

1. **Case-specific information linking the injury to the occurrence of fibromyalgia,**
   Case-specific information might include, but is not limited to:
   - Evidence of a temporal relationship to the worker's industrial injury or occupational exposure (e.g. the injury precedes all symptoms of fibromyalgia or symptoms of potentially crossover disorders such as chronic fatigue syndrome),
   - Documentation that the worker's diagnosis of fibromyalgia meets the American College of Rheumatology's 1990 Criteria for the Classification of Fibromyalgia (see attachment),
   - A biological and clinically justifiable rationale for the relationship between the industrial injury and the occurrence of fibromyalgia. The biological rationale should include a discussion based on accepted principles of biological sciences (anatomy, physiology, biochemistry, etc.) as to how the industrial injury caused the condition.

2. **Scientific studies that address the relationship between individual injuries and the occurrence of fibromyalgia.**
   The provider is encouraged to submit published scientific studies supporting the contention of causality. In 1996, and again in 1997 and 1998, the department reviewed the existing scientific literature on this subject and found insufficient medical data to establish a causal relationship between a traumatic injury or occupational exposure and the development of fibromyalgia. Therefore, it is particularly important that the provider point out any new studies or new analyses of old studies that he or she feels supports a different conclusion regarding causality.

Effective January 1, 1999, State Fund claim managers will automatically request this information from the attending physician whenever fibromyalgia is contended on a claim. Information submitted by the provider to support the causal relationship will be reviewed by department medical staff before a claim adjudication decision is made.

Will the department or self-insurer pay for short-term treatment of fibromyalgia?

Temporary treatment as an aid to recovery
In general, fibromyalgia is not an accepted condition and treatment is not allowed. However, if fibromyalgia is directly retarding recovery of the accepted industrial injury or occupational disease, the department or self-insurer may authorize temporary treatment per WAC 296-20-055. Temporary treatment can be authorized when all of the following conditions are met:

- The accepted industrial injury is not stable,
- Fibromyalgia is directly retarding recovery of the accepted industrial injury or occupational disease, and
- The required documentation is submitted (see authorization and documentation requirements below).

Treatment as an aid to recovery will be authorized for no longer than 90 calendar days. If the worker has reached maximum recovery from the accepted industrial injury or occupational disease prior to the 90-day period, the fibromyalgia treatment will be terminated at that time.

What are the authorization requirements?
The provider must obtain prior authorization to treat fibromyalgia as an aid to recovery. The department or self-insurer will not pay for treatment for fibromyalgia as an unrelated condition unless specifically authorized.

To request prior authorization, the provider must submit the following in writing to the department or self-insurer:
- Adequate documentation that the worker's diagnosis of fibromyalgia meets the American College of Rheumatology's (ACR) 1990 Criteria for the Classification of Fibromyalgia (see attachment A),
- An explanation of how fibromyalgia, as an unrelated condition, is affecting the accepted industrial condition, and
- A treatment plan.

Note: The State Fund's Provider Toll Free staff will not be able to authorize these services.

What type of treatment may be allowed for the temporary treatment of fibromyalgia?
The department or self-insured employer is most likely to approve treatment plans that include conservative, non-invasive treatment that the scientific literature has shown to be effective in the short term. Such treatment includes, but may not be limited to:
- Physical therapy,
- Low dose tricyclic anti-depressants,
- Muscle relaxants on a time-limited basis, or
- Spinal manipulations.

The department or self-insured employer will **not** approve invasive therapies or treatments whose effectiveness has not been documented for even the short-term. The following types of treatment will not be approved for the treatment of fibromyalgia:
- Trigger point injections,
- Methotrexate,
- Opioids, or
- NSAIDS.

Note: Fibromyalgia may coexist with other conditions for which such therapies may be indicated.

What are the documentation requirements?
When treating an unrelated condition, the attending physician must submit a report every 30 days outlining the effect of the treatment on both the unrelated and the accepted industrial conditions.

Because fibromyalgia does not have a unique diagnosis code, we ask that providers use ICD.9 code 729.1 (myalgia) on bills submitted for treatment of fibromyalgia.

Where is more information available?

Temporary treatment of unrelated conditions when retarding recovery
WAC 296-20-055

Criteria for the classification of fibromyalgia
- Enclosed summary, attachment A.
- Frederick Wolfe, et.al., "The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia, Report of the Multicenter Criteria Committee," *Arthritis and Rheumatism*, Vol. 33, No. 2, (February 1990).

ATTACHMENT A

The American College of Rheumatology's 1990 Criteria for the Classification of Fibromyalgia*

For classification purposes, patients will be said to have fibromyalgia if both criteria are satisfied. Widespread pain must have been present for at least 3 months. The presence of a second clinical disorder does not exclude the diagnosis of fibromyalgia.

1. History of widespread pain.

Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain.

2. Pain, on digital palpation, must be present in at least 11 of the following 18 tender point sites:

Occiput - bilateral, at the suboccipital muscle insertions
Low cervical - bilateral, at the anterior aspects of the intertransverse spaces at C5-C7
Trapezius - bilateral, at the midpoint of the upper border
Supraspinatus - bilateral, at origins, above the scapula spine near the medial border
Second rib - bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces
Lateral epicondyle - bilateral, 2 cm distal to the epicondyles
Gluteal - bilateral, in upper outer quadrants of buttocks in anterior fold of muscle
Greater trochanter - bilateral, posterior to the trochanteric prominence
Knee - bilateral, at the medial fat pad proximal to the joint line

Digital palpation should be performed with an approximate force of 4 kg. For a tender point to be considered "positive" the subject must state that the palpation was painful. "Tender" is not to be considered "painful".

* Frederick Wolfe, et.al., "The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia, Report of the Multicenter Criteria Committee", Arthritis and Rheumatism, Vol. 33, No. 2 (February 1990)

Guidelines for Outpatient Prescription of Controlled Substances, Schedules II-IV, For Workers on Time-Loss

L&I, in collaboration with the Washington State Medical Association, has developed two guidelines on the topic of opioids and controlled substances. These two guidelines have some areas of overlap, and some content found in one but not the other guideline. Therefore, both guidelines are included in this publication.

On the following pages you will find the first of the two guidelines, developed in 1992. The second guideline, dealing with opioids, is located in a separate section.

Below is a table summarizing some of the differences between the two guidelines.

It is hoped that clinicians will find both guidelines helpful, depending on the circumstances of each individual patient.

1992 Guideline on Controlled Substances	2000 Guideline on Opioids
• Relates to all controlled substances, not just opioids	• Relates primarily to opioids
• Deals with treatment in the acute and subacute phases	• Deals primarily with chronic phase
• Includes special tools helpful to clinicians, such as: ❑ A useful chart listing examples of Schedule II, III, and IV controlled substances ❑ A list of relative contraindications for the use of controlled substances ❑ 3 hours FREE Category 1 CME with self-assessment test accredited by the American College of Occupational and Environmental Medicine, found in *Attending Doctor's Handbook* ❑ Handy patient education sheet, with a message from the Washington State Medical Association	• Includes special tools helpful to clinicians, such as: ❑ Sample Opioid Treatment Agreement ❑ Functional Progress Form (optional) ❑ Opioid Progress Report (required) ❑ 2 hours FREE Category 1 CME with self-assessment test accredited by the American College of Occupational and Environmental Medicine, found in Provider Bulletin 00-04 ❑ Billing information so providers may be reimbursed for services described
• Includes a guideline only, with no absolute requirements in regulation or law	• Includes the guideline, accompanied by regulations (WACs) and the 1998 Guideline from the Department of Health

Guidelines For Outpatient Prescription Of Controlled Substances, Schedules II-IV, For Workers On Time-Loss

Developed by the Washington State Medical Association and the Washington State Department of Labor and Industries.
Adopted 1992 by the Washington State Medical Association Industrial Insurance and Rehabilitation Committee

INTRODUCTION

Purpose of the Guidelines

Repeated, long-term use of prescription controlled substances for chronic nonmalignant pain may be a factor in the development of long-term disability. This condition may be preventable if at-risk patients and practices are proactively identified and managed appropriately.

It is hoped that the prescribing guidelines listed below will lead to more accurate and timely identification of workers at risk for the development of long-term disability. These guidelines may also be a component of future intervention strategies aimed at preventing long-term disability.

Development of the Guidelines

These guidelines were developed by the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee and the Washington State Department of Labor and Industries. They are based on information from existing prescription guidelines, literature reviews, pharmacologic and medical references, seminars, interviews of experts, and consultations with physicians who have private practices in a wide variety of specialties.

Application of the Guidelines

The guidelines are intended for use in the management of chronic nonmalignant pain. Chronic nonmalignant pain is defined as pain persisting beyond the expected normal healing time for an injury, for which traditional medical approaches have been unsuccessful. Application of these guidelines is intended only for outpatient prescriptions of nonparenteral controlled substances. The nonparenteral routes of administration are considered the only acceptable routes for treating chronic nonmalignant pain in the Washington state workers' compensation system (WAC 296-20-03014).

It is recognized that the guidelines cannot apply uniformly to every patient. Also, the guidelines cannot be the sole determining basis for identifying patients at risk for a drug use problem or currently experiencing a drug use problem. Mere application of the guidelines cannot substitute for a thorough assessment of the patient or medical file by qualified health care professionals. For example, it may be acceptable to prescribe opioids to workers who are gainfully employed and not receiving time-loss. Similarly, the guidelines cannot substitute for detailed prescribing information found in many medical and pharmacologic references.

_____

Date Introduced: 1992

These guidelines will be applied in the workers' compensation setting only. The guidelines will apply only to workers whose injuries occurred after the guidelines are adopted by WSMA and sufficient notice has been given to providers. ***The Department of Labor and Industries may impose sanctions if the guidelines are not followed.***

The guidelines are intended for use by physicians who begin treatment within 6 months of the worker's injury. Patients who have been on controlled substances for prolonged periods and come under the care of a new physician present special problems. These and other problems will be dealt with in a separate publication.

Finally, while the guidelines may not conflict with state or federal laws, by necessity they cannot cover in detail all of the many rules, regulations, and policies published by the various agencies enacting and enforcing these laws.

Table 1

Documentation Recommendations When Controlled Substances Are Prescribed

a. A thorough medical history and physical examination and medical decision-making plan should be documented, with particular attention focused on determining the cause(s) of the patient's pain.

b. A written treatment plan should be documented and should include the following information:
   * a finite treatment plan that does not exceed six weeks.
   * clearly stated, measurable objectives.
   * a list of all current medications (with doses) including medications prescribed by other physicians (whenever possible).
   * description of reported pain relief from each medication.
   * justification of the continued use of controlled substances.
   * documentation of attempts at weaning.
   * explanation of why weaning attempts have failed (including detailed history to elicit information on alcohol and drug use).
   * how the patient's response to medication will be assessed.
   * further planned diagnostic evaluation.
   * alternative treatments under consideration.

c. The risks and benefits of prescribed medications should be explained to the patient and the explanation should be documented, along with expected outcomes, duration of treatment, and prescribing limitations.

d. The treatment plan should be revised as new information develops which alters the plan.

Table 2 **Relative Contraindications For The Use Of Controlled Substances**
1. *History* of alcohol or other substance abuse, or a history or chronic, high dose of benzodiazepine use.
2. *Active* alcohol or other substance abuse.
3. *Borderline* personality disorders.
4. *Mood disorders* (e.g., depression) or psychotic disorders.
5. *Other* disorders that are primarily depressive in nature.
6. *Off work* for more than 6 months.
* Note: When special circumstances seem to warrant the use of these drugs in the types of patients noted above, referral for review is indicated.

General Information

A. Please refer to the "Introduction" for more information on the purpose, development, and application of these guidelines

PHYSICIANS MAY BE HELD ACCOUNTABLE IF THEIR PRESCRIBING PATTERNS FALL OUTSIDE THESE GUIDELINES.

B. Documentation recommendations (as presented in Table 1) should be followed at all times, especially whenever the physician departs from the guidelines listed below.

TREATMENT OF ACUTE PAIN FROM TRAUMATIC INJURIES OR SURGERY (POST-DISCHARGE):

A. Schedule II drugs should be prescribed for no longer than 2 weeks.

B. Schedule III and Schedule IV drugs should be prescribed for no longer than 6 weeks. (See Table 3 for examples of controlled substances.)

TREATMENT OF CHRONIC NON-MALIGNANT PAIN*:

A. **EXTREME CAUTION** should be used in prescribing controlled substances for workers with one or more "Relative Contraindications" (see Table 2). (NOTE: When special circumstances seem to warrant the use of these drugs in the types of patients listed in Table 2, referral for review is indicated.)

B. For patients on a **combination** of opioids and scheduled sedatives:

TREATMENT WITH COMBINATIONS SHOULD USUALLY NOT EXTEND BEYOND 6 WEEKS.

C. For patients on opioids **OR** scheduled sedatives (but not combinations of the two):

TREATMENT SHOULD USUALLY NOT EXTEND BEYOND 3 MONTHS.

D. Consultation or referral to a chronic pain specialist should be considered when any of the following conditions exist:

1. underlying tissue pathology is minimal or absent, **AND** correlation between the structural derangement caused by the original injury and the severity of impairment is not clear;

2. suffering and pain behaviors are present, and the patient continues to request medication; or

3. standard treatment measures have not been successful or are not indicated.

* Defined as pain persisting beyond the expected healing time for an injury, for which traditional medical approaches have been unsuccessful.

Table 3

Examples Of Controlled Substances*

SCHEDULE II	SCHEDULE III	SCHEDULE IV
OPIOIDS: codeine fentanyl (Sublimaze, Innovar) hydromorphone (Dilaudid) levorphanol (Levo-Dromoran) meperidine (Demerol) meperidine w/ Promethazine (Mepergan) methadone (Dolophine) morphine (MS Contin, MSIR, OMS, RMS, Roxanol) oxycodone oxycodone w/ acetaminophen/aspirin (Percocet, Percodan, Roxicet, Roxiprin, Tylox)	OPIOIDS: acetaminophen with codeine (Codalan, Phenaphen 2, 3, 4, Tylenol 2, 3, 4) aspirin with codeine (Empirin 2, 3, 4) hydrocodone hydrocodone w/ acetaminophen/aspirin (Anexsia, Azdone, Bancap, Co-gesic, Damason-P, Dolacet, Duocet, Endal-HD, Hyco-Pap, Hydrocet, Hyphen, Lorcet Plus, Lorcet HD, Lortab, Vicodin, Zydone) nalorphine paregoric	OPIOIDS: propoxyphene (Darvon) propoxyphene w/ acetaminophen/aspirin (Darvocet, Dolene, Wygesic) pentazocine (Talwin)
SEDATIVES: amobarbital (Amytal)** secobarbital (Seconal)** pentobarbital (Nembutal)**	SEDATIVES: any compound containing an unscheduled drug and: amobarbital ** secobarbital** pentobarbital** glutethimide (Doriden) Non-narcotic Analgesic Combinations butalbital with acetaminophen/aspirin (fiorinal)	SEDATIVES: chloral hydrate clorazepate (Tranxene) chlordiazepoxide (Librium) clonazepam (Klonopin) diazepam (Valium) ethchlorvynol (Placidyl) flurazepam (Dalmane) meprobamate (Equanil, Miltown) oxazepam (Serax) paraldehyde (Paral) phenobarbital ** prazepam (Centrax) triazolam (Halcion)

* This table is not intended as an exhaustive listing of controlled substances. A few trade names have been given as examples. This listing should in no way be construed as an endorsement of any medication.

** Barbiturates are not paid for by the Department at any time (except phenobarbital, which is allowed only for seizure disorders).

TO OUR PATIENTS

WHAT YOU SHOULD KNOW ABOUT RULES YOUR DOCTOR MUST FOLLOW TO PRESCRIBE DRUGS THAT MAY BE ADDICTIVE.

The Washington State Medical Association (WSMA) and the Department of Labor and Industries (L&I) believe that it may do you more harm than good to take addicting drugs for a long time.

Guidelines approved by the Washington State Medical Association must be followed by your physician.

SO PLEASE HELP YOUR PHYSICIAN TO HELP YOU -- FOLLOW YOUR DOCTOR'S INSTRUCTIONS CAREFULLY.

THANK YOU!

A message from the Washington State Medical Association.

To the doctor: Please feel free to photocopy this sheet and distribute to your patient, preferably along with your first prescription for controlled substance.

Selected References

The following are a few of the published materials used to prepare these guidelines.

AHFS Drug Information '91, American Hospital Formulary Service, by the American Society of Hospital Pharmacists, Inc., Bethesda, MD, 1991.

"Chronic Opioid Therapy in Nonmalignant Pain," RK Portenoy, Journal of Pain and Symptom Management, Vol. 5, No. 1 (Suppl.) February 1990, pp. S46-S62.

Guidelines for Prescribing Controlled Substances for Chronic Conditions, California Medical Association, San Francisco, CA, April 12, 1985.

"Medications in Low Back Pain," JP Robinson and PB Brown, Physical Medicine and Rehabilitation Clinics of North America, Vol. 2, No. 1, February 1991, pp. 97-125.

"Prescribing Practices for Pain in Drug Dependence: A Lesson in Ignorance," LM Halpern and JP Robinson, Controversies in Alcoholism and Substance Abuse, The Haworth Press, Inc., 1986.

"Unlocking the Secrets of Pain — The Treatment — A New Era," JD Loeser, Medical and Health Annual Encyclopedia Britannica, 1988 pp 120-31.

Guidelines for Outpatient Prescription of Oral Opioids for Injured Workers with Chronic, Noncancer Pain

L&I, in collaboration with the Washington State Medical Association, has developed two guidelines on the topic of opioids and controlled substances. These two guidelines have some areas of overlap, and some content found in one but not the other guideline. Therefore, both guidelines are included in this publication.

On the following pages you will find the second of the two guidelines, developed in May, 2000. The first guideline, dealing with controlled substances, is located in a separate section.

Below is a table summarizing some of the differences between the two guidelines.

It is hoped that clinicians will find both guidelines helpful, depending on the circumstances of each individual patient.

1992 Guideline on Controlled Substances	2000 Guideline on Opioids
• Relates to all controlled substances, not just opioids	• Relates primarily to opioids
• Deals with treatment in the acute and subacute phases	• Deals primarily with chronic phase
• Includes special tools helpful to clinicians, such as: ❑ A useful chart listing examples of Schedule II, III, and IV controlled substances ❑ A list of relative contraindications for the use of controlled substances ❑ 3 hours FREE Category 1 CME with self-assessment test accredited by the American College of Occupational and Environmental Medicine, found in *Attending Doctor's Handbook* ❑ Handy patient education sheet included, with a message from the Washington State Medical Association	• Includes special tools helpful to clinicians, such as: ❑ Sample Opioid Treatment Agreement ❑ Functional Progress Form (optional) ❑ Opioid Progress Report (required) ❑ 2 hours FREE Category 1 CME with self-assessment test accredited by the American College of Occupational and Environmental Medicine, found in Provider Bulletin 00-04 ❑ Billing information so providers may be reimbursed for services described
• Includes a guideline only, with no absolute requirements in regulation or law	• Includes the guideline, accompanied by regulations (WACs) and the 1998 Guideline from the Department of Health

GUIDELINES FOR OUTPATIENT PRESCRIPTION OF ORAL OPIOIDS FOR INJURED WORKERS WITH CHRONIC, NONCANCER PAIN

May 1, 2000

These guidelines were developed by the Washington State Department of Labor and Industries (L&I) in collaboration with the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee. These guidelines are intended to help doctors follow the 1998 *Guidelines for Management of Pain* issued by the Washington State Department of Health (DOH), and to apply the DOH guidelines to the care of injured workers with chronic, noncancer pain.

WHAT'S INSIDE

Date Introduced: May 2000

HELPFUL TOOLS

Are there tools to help me follow all relevant recommendations?

Reference: Provider Bulletin 00-04;

INTRODUCTION

Chronic, noncancer pain can be a complex and difficult management problem for both patient and physician. Chronic, noncancer pain may develop after an acute injury episode and is defined as pain that persists 2 - 4 months from the date of injury.

These guidelines are intended to help doctors to follow the 1998 *Guidelines for Management of Pain* issued by the Washington State Department of Health (DOH), and to apply the DOH guidelines to the care of injured workers with chronic, noncancer pain.

Long-term opioid use for chronic, noncancer pain is based on changing community standards and a body of evidence based on case reports of series of patients. There are few well-controlled or randomized controlled studies on the use of opioids in chronic pain states. There are no studies evaluating the effects of opioid use for chronic, noncancer pain exclusively in a worker's compensation population.

Even in the absence of strong research evidence, the community standard for the treatment of chronic, noncancer pain is changing. Findings from case reports do suggest that with appropriate patient selection and careful monitoring, opioid treatment can be effectively provided. Thus, a trial of opioid medications may be warranted.

These guidelines were developed by the Washington State Department of Labor and Industries (L&I) in collaboration with the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee. The guidelines are based on information from existing guidelines, extensive literature reviews, pharmacologic and medical references, interviews of experts and consultations with physicians in a wide variety of specialties. Careful, regularly documented compliance with these guidelines is necessary for the safety of injured workers, and to further the goal to return injured workers to health and to work.

Please note: The medical care a patient receives is a matter of choice for the patient to make in consultation with a treating physician. This principle is the same in cases with and without workers' compensation issues. Payment for medical care involves issues that may be distinct from treatment decisions. The Department of Labor and Industries pays for only that medical care which meets the requirements of the Washington Administrative Code and cannot pay for opioids once the patient reaches maximum medical improvement.

For which patients should I use these guidelines and why were the guidelines developed?
Please use these guidelines for all injured workers with chronic pain who are taking opioids.

These guidelines are intended to supplement the 1998 *Guidelines for Management of Pain* issued by the Washington State Department of Health (see Appendix 1, page 95). L&I endorses and encourages compliance with the DOH *Guidelines*. Since the *Guidelines for Management of Pain* were issued, problems of both under-treatment and over-treatment with controlled substances continue. L&I feels there is a need to make it easier for providers to follow the DOH *Guidelines* while treating injured workers, especially the sections on documentation.

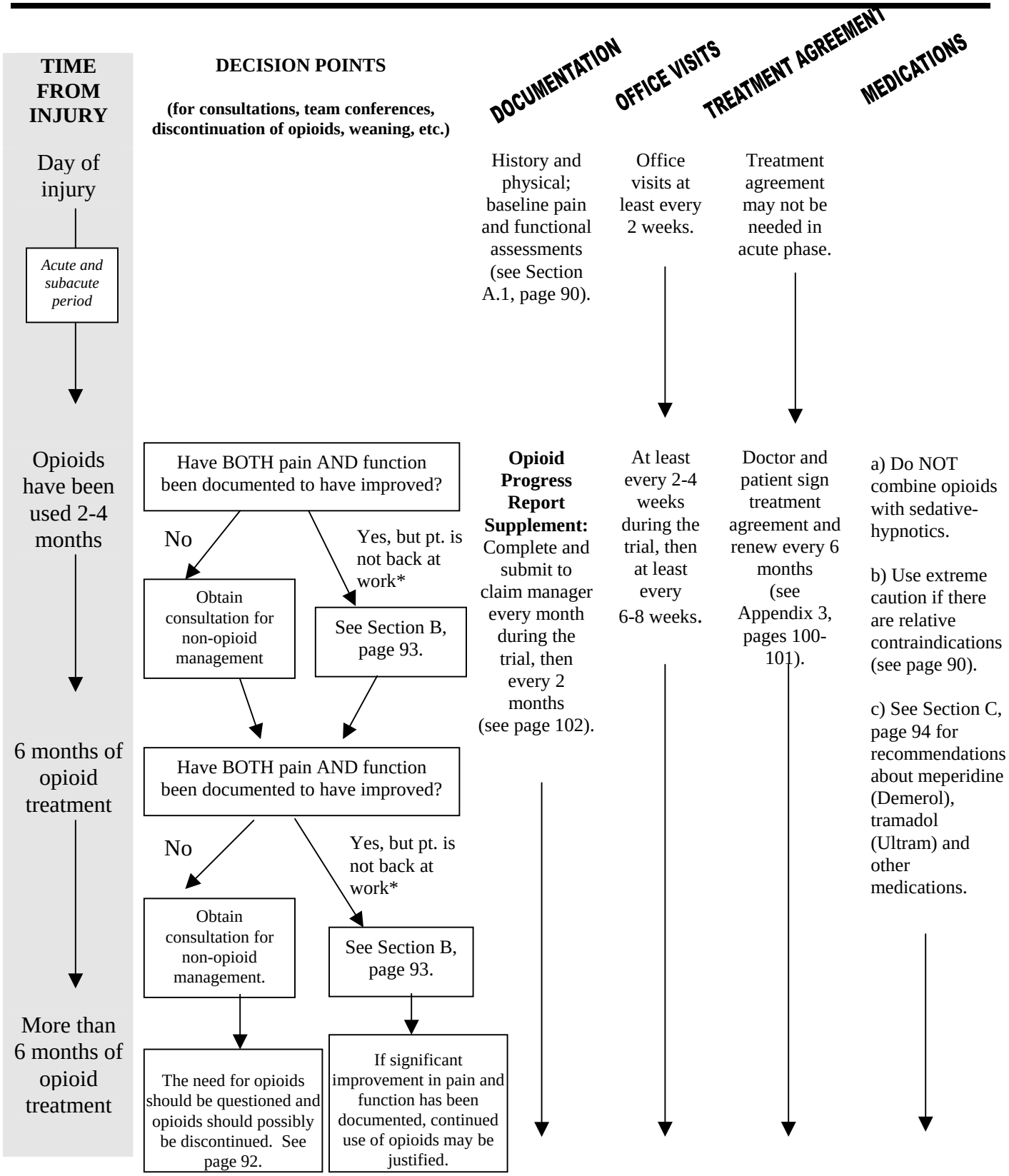
Also, L&I must consider factors such as whether care is curative or rehabilitative and whether a worker has reached a stable plateau from which further recovery is not expected (maximum medical improvement or MMI). *

In addition, operating heavy machinery, driving motor vehicles and other work activities may be dangerous to your patient and to his/her co-workers if controlled substances are being used. Your patient's livelihood may be affected for this reason.

Such considerations created a need to supplement the DOH *Guidelines for Management of Pain* for the worker population.

** For details, please refer to L&I's Medical Aid Rules (WAC 296-20-03019 and WAC 296-20-03022).*

FLOWCHART SUMMARIZING OPIOID GUIDELINES



* *If pain and function have improved and patient has returned to work, please refer to Section F.8. "Assessment and Monitoring" of the DOH Guidelines on page 97.*

SECTION A. ASSESSMENT, MANAGEMENT AND DOCUMENTATION

1. How do I assess whether a formal trial of opioids for chronic pain is indicated?

You should address several questions to decide if a formal trial of opioids for chronic pain is indicated: 1) Are there reasonable alternatives other than opioids? 2) Is the patient likely to improve with opioids? and 3) Is the patient likely to abuse opioids or have other adverse outcomes? See Table 1 below for guidance on the latter two questions.

For guidance in the acute and subacute phases, refer to the "Guidelines for Outpatient Prescription of Controlled Substances for Workers on Time-Loss," developed in 1992 by L&I in collaboration with the Washington State Medical Association. These may be found in the *Attending Doctor's Handbook*, obtained by calling 1-800-848-0811.

Beyond 2-4 months of acute/subacute opioid use, the following assessment is strongly recommended:

a) Perform a baseline history and physical, including pain history and the impact of pain on the patient, a complete exam, review of previous diagnostic and therapeutic results and an assessment of co-existing conditions.
b) Obtain relevant baseline clinical or laboratory studies and/or urine drug screen, as indicated.
c) Based on the results of your assessment, identify the pain diagnosis. (See Table 1.)
d) Baseline pain and functional assessments should be documented. You may find it helpful to use a form like the attached *Opioid Progress Report Supplement* on page 102. ***Function includes***

(Continued on next page.)

TABLE 1. HOW TO ASSESS WHETHER AN OPIOID TRIAL IS INDICATED

1) IS THE PATIENT LIKELY TO IMPROVE?

MAY IMPROVE	PROBABLY WILL NOT IMPROVE
1) Patient has taken opioids in the acute and subacute phases with some improvement in pain and function.	1) Patient has taken opioids in the acute and subacute phases with NO improvement in pain and function (assuming appropriate dosing, etc.).
2) Other conservative measures have failed (NSAIDs, etc.) and opioids have not been tried.	2) The pain diagnosis falls into the category of somatoform disorder. A consultation should be considered to address the underlying problem. In particular, conversion disorder, somatization disorder, or pain disorder associated with psychological factors (DSM-IV 307.80) is associated with poor response to opioids.
3) Your pain diagnosis falls into one of the following three categories: a) Nociceptive pain (for example, ischemia, tissue destruction, arthritis, cancer, arachnoiditis). b) Neuropathic pain (for example, sciatica, carpal tunnel syndrome, trigeminal neuralgia, post-herpetic neuralgia, phantom limb pain). c) Mixed nociceptive and neuropathic pain.	

2) IS THE PATIENT LIKELY TO ABUSE OPIOIDS OR HAVE OTHER ADVERSE OUTCOMES?

The risk of abuse or adverse outcome is high if any of the following are present:

1) History of alcohol or other substance abuse, or a history of chronic, high dose benzodiazepine use.
2) Active alcohol or other substance abuse.
3) Borderline personality disorders.
4) Mood disorders (e.g., depression) or psychotic disorders.
5) Other disorders that are primarily depressive in nature.
6) Off work for more than 6 months.
7) Poor response to opioids in the past.

Note: When special circumstances seem to warrant the use of these drugs in the types of patients noted above, referral for review is indicated.

social, physical, psychological, daily and work activities.

e) Assess the worker's ability to participate in a return-to-work program, for example, work-hardening and vocational services.

f) Assess likelihood the patient can be weaned from opioids in the event there is no improvement in pain and function.

g) Decide whether you have the expertise to conduct a formal opioid trial for chronic pain. If not, make an appropriate referral.

Please note: In order for the Department of Labor & Industries or the self-insurer to pay for the opioid trial, the physician must submit a report no later than 30 days after beginning such treatment. (See WAC 296-20-03020 for details on the requirements of this report.)

2. How should I manage a formal trial of opioids for chronic pain?

The following general parameters should guide the attending physician's plan of care:

a) **Second opinion:** Consider a second opinion before planning the trial of opioids to assess whether a trial is indicated, and if so, how it should be conducted.

b) **Documentation:** ***You should use the one-page Opioid Progress Report Supplement, page 100.*** This will help you comply with all documentation requirements of the Department of Labor and Industries. (See WAC 296-20-03021 and 296-20-03022.)

Using the one-page Opioid Progress Report Supplement will also serve as a step-by-step guide to remind you and your patient to address a number of key issues, such as the treatment agreement, screening for addiction, return-to-work efforts, assessment of functional progress, consultations, medication history, treatment plan, etc.

c) **Contingency plan:** Plan ahead of time for both of these possibilities:

1) The patient needs to be weaned from opioids because there has been no improvement in pain and function.

2) Continuation of opioids beyond maximum medical improvement is indicated, and other forms of payment for the medications will be needed.

d) **Treatment agreement:** You and your patient should together sign a treatment agreement that outlines: the risks and benefits of opioid use, the conditions under which opioids will be prescribed, the physician's need to document overall improvement in function, and worker responsibilities (See Appendix 3, pages 100-101, Sample Opioid Treatment Agreement).

Safety risks: Patients should especially be warned about potential side effects of opioids such as increased reaction time, clouded judgment, drowsiness and tolerance. Also, they should be warned about the possible danger associated with the use of opioids while operating heavy equipment or driving.

e) **Helping your patient return to work:** You should participate in a team conference with your patient, the employer (or potential new employers), the claim manager, the vocational counselor and others (preferably face-to-face) to explore return-to-work options. Which parties need to be involved will vary with each situation. Phone conferences often work well.

For more information on resources available to you, see pages 9 – 14 of the Attending Doctor's Handbook (available at 1-800-848-0811).

f) **Principles for prescription of opioids:** You should follow these general principles:

1) **Single prescribing physician:** There should be a single prescribing physician for all controlled substances.

2) **Single pharmacy:** You should use a single pharmacy for prescription filling (whenever possible).

3) **Lowest possible dose:** The lowest possible effective dose should be used to initiate therapy, and should be titrated, as needed to minimize both pain and medication side effects and maximize pain management and increased functioning.

4) **Appearance of misuse of medications:** Be sure to watch out for and document any appearance of misuse of medications. Acquisition of drugs from other physicians, uncontrolled dose escalation or other aberrant behaviors must be carefully assessed. In all such patients, opioid use should be reconsidered and additional, more rigid

guidelines applied if opioids continue. In some cases, tapering and discontinuation of opioid therapy will be necessary.

g) **Visit frequency:** Visits initially at least every 2 weeks for the first 2-4 months of the trial, then at least once every 6-8 weeks while receiving opioids.

h) **Consultations:** You should request a consultation if:

1) A dose in excess of 100-150 mg of oral morphine daily or its equivalent (for example, 45 mg of MS Contin every 8 hours) is being used;
2) Pain and functional status have not substantially improved after 3 months of opioid treatment;
3) A patient has a history of chemical dependency; or
4) A patient appears to have significant problems with depression, anxiety or irritability (a psychologic consultation may be indicated in these cases).

i) **Laboratory studies and drug screens:** Remember to order relevant ongoing clinical or laboratory studies (especially liver or kidney function screens), including drug screens, as indicated.

j) **Discontinuation vs. continuation of opioids:** After 6 months of a well-designed opioid trial, a physician should determine whether opioid therapy is appropriate for the patient, in accordance with the following:

1) If there has not been an overall improvement in function, opioids should usually be discontinued. (If there are extenuating circumstances that justify further use of opioids after 6 months of an opioid trial, these should be described in detail.)

2) If the patient has returned to work or has demonstrated substantial improvement both in function and reported pain level during a 6-month opioid trial, reasonable doses of opioids could continue. However, you and your patient should understand that state law forbids L&I from paying for opioids once the patient reaches maximum medical improvement. Please refer to L&I's *Medical Aid Rules* WAC 296-20-03019 through 296-20-03024 for further details. You should speak with your patient about other sources of payment for opioids when L&I can no longer pay. With this in mind, you should re-evaluate the need for opioids every two months, using techniques such as weaning and/or substitution of alternative treatments.

3) **Weaning time:** Weaning can be done safely by way of a slow taper. Patients who undergo intensive treatment programs in a pain center
or a drug rehabilitation center can be tapered off opioids in 1-2 weeks. Patients being treated in an office-based practice should be tapered more slowly, but the taper should never take more than 3 months.

SECTION B. LONG-TERM ISSUES

1. What should I do if I have a patient who has *already* been on opioids for 6 months or more and is not back at work (or if I accept a *new* patient like this)?

If a patient has already received opioids for six months or more, you should do the following:

a) **Re-assess:** Perform a thorough re-assessment of the patient to see if anything has been missed.

1) Is the original diagnosis still present? Are there additional diagnoses that may contribute to the pain?

2) Has the patient been given other medications for management of pain? If so, how effective were they, what side effects were experienced and how severe were the side effects?

3) Has the patient tried other treatment methods or consulted with other specialists? If so, what alternative methods have been tried, length of alternative treatments, effectiveness, and/or specialist recommendations and effectiveness of those recommendations?

4) Has there been functional improvement since opioids were started? Try to quantify the improvement.

5) Would a psychological or psychiatric evaluation, completed by a psychiatrist or psychologist experienced in evaluating chronic pain patients, be helpful or necessary for you to determine effective pain management for this patient? Or has the patient completed a similar evaluation within the last 3-6 months? Psychosocial issues include motivation, attitude about pain/work, return-to-work options, home life, etc.

6) Has screening for elements of addiction been completed? Special caution should be exercised in patients with a history of substance abuse that cannot be attributed to a past mistaken diagnosis of addiction because this patient previously used opiates for pain management. Have you reviewed prior medical records, including L&I medical records and drug summaries? A drug summary may be obtained from the claim manager.

7) Review Sections A2, C1 and C2 for guidance on re-assessment and documentation. The essential material in these sections, particularly the treatment plan and its relationship to recovery, should be covered in your summary.

b) **Summarize:** Provide the insurer and others involved in the patient's care with a written summary of the case. Special attention should be given to the history of opioid use (how long, in what doses, etc.). Give a clear statement of your rationale if you think opioid treatment should continue.

c) **Help the patient return to work**: You should participate in a team conference with the patient, the employer (or potential new employers), the claim manager, the vocational counselor and others (preferably face-to-face) to explore return-to-work options. Which parties need to be involved will vary with each situation. Phone conferences sometimes work well.

For more information on resources available to you and how to bill for these services, see pages 9 – 14 of the Attending Doctor's Handbook (available at 1-800-848-0811).

d) **Triage:** If the patient has been treated with opioids for 6 months or more, you should ***automatically*** review the case as described in a) through d). At that point the physician should choose one of three pathways:

1) Modify the treatment plan to achieve optimum opioid benefit. Many patients like this will be taking combinations of medications that don't offer optimal pain control.

2) Discontinue opioid therapy.

3) Continue in opioid therapy.

In the third pathway, plans could be made to eventually move from the long-term opioid pathway up to one of the other pathways.

SECTION C. PRECAUTIONS IN PRESCRIBING

1. What precautions should I take when prescribing opioids?

a) ***DO NOT USE:***

Opioids in combination with sedative-hypnotics (such as benzodiazepines or barbiturates) for chronic, noncancer pain.

(There may be specific indications for such combinations, such as the co-existence of spasticity. In such cases, a consultation is strongly recommended.)

b) ***Use of these medications is NOT RECOMMENDED:***

1. Meperidine, which should not be prescribed for chronic pain.
2. Tramadol (Ultram) in combination with other opioids.
3. Carisoprodol (Soma).
4. Combination agonists and mixed agonists/antagonists. Mixed agonists/antagonists include such drugs as butorphanol (Stadol); dezocine (Dalgan), nalbuphine (Nubain) and pentazocine (Talwin).
5. Barbiturates (except if used to treat a seizure disorder).
6. Outpatient prescriptions of parenteral dosage forms of any drug.

c) ***Use caution when prescribing:***

1. Acetaminophen in doses greater than 4 grams (including, for example, combinations of drugs that include both an opioid and acetaminophen).
2. Cyclobenzaprine (Flexeril) in combination with tricyclic antidepressants (both share the same toxic potential).
3. Nonopioid drugs concomitantly with combination opioids (e.g., Tylenol given with Percocet).
4. Tramadol (Ultram) to patients at risk for seizures and/or who are also taking drugs which can precipitate seizures (e.g., SSRI antidepressants, tricyclic antidepressants).
5. Opioids, including tramadol, to patients with a prior or active history of chemical dependency.

d) Other recommendations include:

- Drug therapy should be individualized to the patient's specific pain condition and chosen on the basis of each drug's pharmacologic activity.
- Maintain patients on as few medications as possible. Drug interactions and adverse events increase as the number of medications in a regimen increases.
- Use adjuvant medications that are specific for a given pain condition.
- If possible, titrate only one drug at a time, while observing the patient for additive effects. Inappropriate medications should be tapered while initiating an appropriate pharmacologic regimen.

2. What signs may you see in a person with a prescription opioid problem?

The following guidelines were developed in a pain clinic setting. These guidelines may be a useful monitoring tool in managing chronic pain patients in your office setting. A patient may qualify as a prescription opiate abuser by meeting three or more of the criteria listed below. Physicians are encouraged to seek consultations (addictionologist, pain clinic, etc.) if 3 or more of these criteria are met. The patient:

a) Displays an overwhelming focus on opioid issues. For example, discussion of opioids occupies a significant portion of the visit and impedes progress with other issues regarding the patient's pain. This behavior persists beyond the third clinic session.
b) Has a pattern of early refills (3 or more) or escalating drug use in the absence of physician direction to do so.
c) Generates multiple telephone calls or visits to the office to request more opioids, early refills, or problems associated with the opioid prescription. A patient may qualify with fewer visits if he or she creates a disturbance with the office staff.
d) Demonstrates pattern of prescription problems for a variety of reasons that may include lost medications, spilled medications or stolen medications.
e) Has supplemental sources of opioids obtained from multiple providers, emergency rooms or illegal sources.
f) Has illicit drugs on urine screen.

APPENDIX 1

DEPARTMENT OF HEALTH GUIDELINES FOR MANAGEMENT OF PAIN

Washington State Department of Health
Medical Quality Assurance Commission
Adopted 1998

A. Introduction

There are widespread concerns among patients throughout the state about access to appropriate medical treatment, including opioid therapy, for addressing chronic intractable pain. Similarly, providers express apprehensions about challenges by state disciplinary authorities when prescribing opioid analgesics for indicated medical treatment when serving the legitimate medical needs of pain patients. The undertreatment of chronic pain due to concerns about addiction and drug diversion affect the public health, safety, and welfare. There is a need for guidance which would: a) encourage appropriate treatment for pain management; b) reduce providers' fear of injudicious discipline; and c) protect the public from inappropriate prescribing practices and diversion.

B. Purpose statement

The Secretary of the Department of Health recommends the uniform adoption, by appropriate state regulatory authorities, of the following guidelines when managing pain. It is not the intent of these guidelines to define complete standards of acceptable medical care in the treatment of pain patients. These guidelines are not intended to direct clinical practice parameters. It is the intent that providers will have confidence that these guidelines are the standard by which opioid usage is evaluated.

C. Policy statement

Under generally accepted standards of medical practice, opioids may be prescribed for the treatment of acute or chronic pain including chronic pain associated with cancer and other noncancer pain conditions. Prescribing opioids requires special consideration. It is the position of the Department of Health that opioids may be prescribed, dispensed, or administered when there is an indicated medical need without fear of injudicious discipline.

D. Guidelines for opioid usage

1) Acute pain

Opioids are useful for patients with acute pain such as surgery, burn, or trauma. The goal of such treatment is to provide adequate and timely pain management to the patient. Side effects of opioids that are difficult to treat may occur and must be balanced against the benefits of pain relief. The provider should, for any patient who has a history of alcoholism or other drug addictions, carefully monitor medications and when available seek appropriate consultation.

2) Chronic Pain Associated with Cancer

Chronic pain associated with cancer may often be successfully managed with opioids. If use of opioids is the primary analgesic strategy, adequate doses should be given frequently enough to keep the patient continuously comfortable. Addiction is rare in patients with cancer pain; tolerance and physical dependency are often unavoidable and should not interfere with opioid prescribing. Not all pain in patients with cancer is responsive to opioids; alternative strategies for managing the pain should also be made available.

3) Other Chronic Pain Conditions

Opioid analgesics can be useful in the treatment of patients with intractable noncancer pain especially, where efforts to remove the cause of pain or to treat it with other modalities have failed or were not fully successful. The pain of such patients may have a number of different etiologies and may require several modalities. In addition, the extent to which pain is associated with psychological, physical, and social impairment varies greatly. Therefore, the selection for a trial of opioid therapy should be based on a careful assessment of the pain as well as the impairment experienced by the patient. Continuation of opioid therapy should be based on the provider's evaluation of the results of treatment, including the degree of pain relief, changes in psychological, physical, and social functioning, and appropriate utilization of health services. Providers are encouraged to obtain consultation from providers who are knowledgeable in pain management, particularly

when managing patients with a history of alcohol abuse or previous chronic opioid use.

E. Definitions

1. **Addiction** – A disease process involving use of psychoactive substances wherein there is loss of control, compulsive use, and continued use despite adverse social, physical, psychological, or spiritual consequences.
2. **Physical dependence** – A physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is not necessarily associated with full blown addiction, and condition does not always equate with addiction.
3. **Psychological dependence** – A subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.
4. **Tolerance** – State in which an increased dosage of a psychoactive substance is needed to produce a desired effect.
5. **Withdrawal syndrome** – The onset of a predictable constellation of signs and symptoms following the abrupt discontinuation of, or rapid decrease in, dosage of a psychoactive substance.
6. **Acute pain** – An essential biologic signal of the potential for or the extent of injury. It is usually short-lived and is associated with hyperactivity of the sympathetic nervous system; e.g. tachycardia, increased respiratory rate and blood pressure, diaphoresis, and papillary dilation. The concurrent affect is anxiety.
7. **Chronic pain** – Pain persistent beyond expected healing time and often cannot be ascribed to a specific injury. Chronic pain may not have a well-defined onset and by definition does not respond to treatment directed at its causes.
8. **Intractable pain in a noncancer patient** – Pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts.

F. Guidelines for assessment and documentation in noncancer pain

Alternative strategies for managing pain must be explored. If alternative strategies for managing the pain are unsuccessful, long term opioid therapy can be added. The goal is not merely to treat the symptoms of pain, but to devise pain management strategies which deal effectively with all aspects of the patient's pain syndrome, including psychological, physical, social, and work-related factors. Documentation in the patient's medical record should include:

1. **History and medical examination** – A complete physical examination and comprehensive medical history should be part of the active treatment record including, but not limited to, a review of past pain treatment outcomes and any history of addiction risks to establish a diagnosis and treatment plan.
2. **Diagnosis and medical indication** – A working diagnosis must be delineated, which includes the presence of a recognized medical indication for the use of any treatment or medication.
3. **Written treatment plan with recorded measurable objectives** – The plan should have clearly stated, measurable objectives, indication of further planned diagnostic evaluation, and alternative treatments.
4. **Informed consent** – Discussions of risks and benefits should be noted in some format in the patient's record.
5. **Periodic reviews and modifications indicated** – At these periodic reviews, the provider should reassess the treatment plan, the patient's clinical course, and outcome goals with particular attention paid to disease progression, side effect and emergence of new conditions.
6. **Consultation** – The treating provider should be knowledgeable and competent in referring patients to the appropriate specialist if needed and noting in the patient's record the treating provider's interpretation of the consultation reports. Additionally, a new patient with evidence of at-risk patterns of opioid usage should be evaluated by a knowledgeable specialist.
7. **Records** – The provider should keep accurate and complete records documenting the dates and clinical findings for all evaluations, consultations, treatments, medications and patient instructions.
8. **Assessment and monitoring** – Some patients with chronic pain not associated with cancer may be at risk of developing increasing opioid consumption without objective improvement in functional status. Subjective reports by the patient should be supported by objective observations. Objective measures in the patient's condition are determined by an ongoing

assessment of the patient's functional status, including the ability to engage in work or other gainful activities, patient consumption of health care resources, positive answers to specific questions about the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient as observed by the physician.

Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a disease with behavior characterized by psychological dependence and aberrant drug related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts merely because they are being treated with opioids.

The physician is responsible for monitoring the dosage of the opioid. Monitoring includes ongoing assessment of patient compliance with drug prescriptions and related treatment plans. Communication between health care providers is essential. The patient should receive long term analgesic medications from one physician and where possible one pharmacy. All providers should be particularly cautious with patients with a history of alcoholism or other drug addiction when prescribing long term opioids. Consults with addiction specialists are recommended.

G. Patient Responsibilities

1. It is the patient's responsibility to candidly provide the treatment provider with a complete and accurate treatment history, including past medical records, past pain treatment and alcohol and other drug addiction history.
2. The patient should participate as fully as possible in all treatment decisions.
3. The patient and family members, if available, should inform the prescriber of all drug side effects and concerns regarding prescription drugs.
4. The patient should not use other psychoactive agents, including alcohol, naturopathic products or over-the-counter drugs without agreement to the prescriber.
5. The patient should use the same name when receiving medical care to assure completeness of the medical record.
6. The patient should demand respect and expect to be believed.
7. The patient should keep an open mind and be willing to work with the treatment provider, including:
    a. negotiate with the provider to arrive at an acceptable plan of treatment;
    b. be open in trying alternative treatment strategies; and
    c. follow the treatment provider's instructions precisely.
8. The patient should, where possible, get all central nervous system medications from one provider. If this is not possible, the patient should inform each provider of all medications he/she is receiving.
9. The patient should, where possible, have all prescriptions filled at a single pharmacy.
10. The patient should not horde, share, or sell medications.
11. The patient should be aware that providers may, by law, share information with other providers about the patient's care.

APPENDIX 2

HOW WERE THESE GUIDELINES DEVELOPED?

These guidelines were developed by the Washington State Department of Labor and Industries (L&I) in collaboration with the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee. The WSMA is charged by the Washington Administrative Code with the responsibility and authority to advise L&I on issues relating to medical care of injured workers.

Beginning in 1998 numerous meetings of the Treatment Guidelines Subcommittee were devoted to discussion of medical, legal, adjudicative and other aspects of chronic pain management. The subcommittee consisted of physicians representing a variety of specialties, including anesthesiology, internal medicine, neurology, occupational medicine, orthopedic surgery, physical medicine and rehabilitation, and plastic surgery, among others. The subcommittee included one doctor who had participated in the creation of the Department of Health "Guidelines for Management of Pain."

The subcommittee carefully reviewed the medical literature on the topic of opioids and their use for chronic noncancer pain. The subcommittee refined a series of drafts, then used a consensus process to arrive at a draft for wider distribution and comment.

The subcommittee solicited and received comments from dozens of authorities from many parts of the United States. The authorities represented a spectrum of disciplines, specialties and perspectives, including non-physicians such as representatives of patient advocacy organizations.

After further discussion and incorporation of changes based on stakeholder input, the subcommittee presented a final draft to the WSMA and recommended that the WSMA approve the guidelines. The WSMA approved the guidelines in April 1999. Additional comments were received, and the WSMA approved a number of enhancements to the guidelines. These guidelines are intended to be reviewed and amended on a regular basis depending on emerging scientific data and on changing community standards.

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APPENDIX 3

SAMPLE OPIOID TREATMENT AGREEMENT

Patient Name:_____ **Date:**_____

Opioid (narcotic) treatment for chronic pain is used to reduce pain and improve what you are able to do each day. Along with opioid treatment, other medical care may be prescribed to help improve your ability to do daily activities. This may include exercise, use of non-narcotic analgesics, physical therapy, psychological counseling or other therapies or treatment. Vocational counseling may be provided to assist in your return to work effort.

To the doctor: Keep signed originals in your file; give a photocopy to the patient. Renew at least every 6 months.

I, _____, understand that compliance with the following guidelines is important in continuing pain treatment with Dr. _____.

1. I understand that I have the following responsibilities:
   a. I will take medications only at the dose and frequency prescribed.
   b. I will not increase or change medications without the approval of this doctor.
   c. I will actively participate in RTW efforts and in any program designed to improve function (including social, physical, psychological and daily or work activities).
   d. I will not request opioids or any other pain medicine from physicians other than from this doctor. This doctor will approve or prescribe all other mind and mood altering drugs.
   e. I will inform this doctor of all other medications that I am taking.
   f. I will obtain all medications from one pharmacy, when possible known to this doctor with full consent to talk with the pharmacist given by signing this agreement.
   g. I will protect my prescriptions and medications. Only one lost prescription or medication will be replaced in a single calendar year. I will keep all medications from children.
   h. I agree to participate in psychiatric or psychological assessments, if necessary.
   i. If I have an addiction problem, I will not use illegal or street drugs or alcohol. This doctor may ask me to follow through with a program to address this issue. Such programs may include the following:
      - 12-step program and securing a sponsor
      - Individual counseling
      - Inpatient or outpatient treatment
      - Other: _____

2. I understand that in the event of an emergency, this doctor should be contacted and the problem will be discussed with the emergency room or other treating physician. I am responsible for signing a consent to request record transfer to this doctor. No more than 3 days of medications may be prescribed by the emergency room or other physician without this doctor's approval.

3. I understand that I will consent to random drug screening. A drug screen is a laboratory test in which a sample of my urine or blood is checked to see what drugs I have been taking.

4. I will keep my scheduled appointments and/or cancel my appointment a minimum of 24 hours prior to the appointment.

5. I understand that this doctor may stop prescribing opioids or change the treatment plan if:
   a. I do not show any improvement in pain from opioids or my physical activity has not improved.
   b. My behavior is inconsistent with the responsibilities outlined in #1 above.
   c. I give, sell or misuse the opioid medications.
   d. I develop rapid tolerance or loss of improvement from the treatment.
   e. I obtain opioids from other than this doctor.
   f. I refuse to cooperate when asked to get a drug screen.
   g. If an addiction problem is identified as a result of prescribed treatment or any other addictive substance.
   h. If I am unable to keep follow-up appointments.

_____ _____

Patient Signature **Date** **Physician Signature** **Date**

SAMPLE OPIOID TREATMENT AGREEMENT (*continued*)

YOUR SAFETY RISKS WHILE WORKING UNDER THE INFLUENCE OF OPIOIDS:

You should be aware of potential side effects of opioids such as decreased reaction time, clouded judgment, drowsiness and tolerance. Also, you should know about the possible danger associated with the use of opioids while operating heavy equipment or driving.

SIDE EFFECTS OF OPIOIDS:

- Confusion or other change in thinking abilities
- Nausea
- Constipation
- Vomiting
- Problems with coordination or balance that may make it unsafe to operate dangerous equipment or motor vehicles
- Sleepiness or drowsiness
- Breathing too slowly – overdose can stop your breathing and lead to death
- Aggravation of depression
- Dry mouth

THESE SIDE EFFECTS MAY BE MADE WORSE IF YOU MIX OPIOIDS WITH OTHER DRUGS, INCLUDING ALCOHOL.

RISKS:

- Physical dependence. This means that abrupt stopping of the drug may lead to withdrawal symptoms characterized by one or more of the following:

Runny nose	Difficulty sleeping for several days
Diarrhea	Abdominal cramping
Sweating	'Goose bumps'
Rapid heart rate	Nervousness

- Psychological dependence. This means it is possible that stopping the drug will cause you to miss or crave it.
- Tolerance. This means you may need more and more drug to get the same effect.
- Addiction. A small percentage of patients may develop addiction problems based on genetic or other factors.
- Problems with pregnancy. If you are pregnant or contemplating pregnancy, discuss with your physician.

PAYMENT OF MEDICATIONS:

State law forbids L&I from paying for opioids once the patient reaches maximum medical improvement. You and your doctor should discuss other sources of payment for opioids when L&I can no longer pay.

RECOMMENDATIONS TO MANAGE YOUR MEDICATIONS:

- Keep a diary of the pain medications you are taking, the medication dose, time of day you are taking them, their effectiveness and any side effects you may be having.
- Use of a medication box that you can purchase at your pharmacy that is already divided in to the days of the week and times of the day so it is easier to remember when to take your medications.
- Take along only the amount of medicine you need when leaving home so there is less risk of losing all your medications at the same time.

I have read this document, understand and have had all my questions answered satisfactorily. I consent to the use of opioids to help control my pain and I understand that my treatment with opioids will be carried out as described above.

Patient Signature	**Date**	**Physician Signature**	**Date**

This is where the OPIOID PROGRESS REPORT SUPPLEMENT form goes.

This is where the FUNCTIONAL PROGRESS FORM goes.

Summary of policy changes

Until recently, the Washington Administrative Code (WACs) prohibited payment for opioids prescribed to injured workers for the treatment of chronic pain. Those rules were changed effective January 20, 2000. The department or self-insurer can now pay for opioids to treat chronic, noncancer pain as long as the worker:

- Has substantial reduction in pain *and* continuing substantial improvement in function, and
- Has not reached maximum medical improvement.

Summary of authorization and documentation requirements

In accordance with these new rules on the payment for opioids to treat chronic, noncancer pain, the treating physician is required to submit two new reports and a treatment agreement. These reports are needed for the department or self-insurer to authorize payment and to monitor your patient's progress. The *Opioid Progress Report Supplement* is required in addition to regular 60-day progress reports. Please review the table below to see, at a glance, more information about this required documentation. Copies of the *Opioid Progress Report Supplement* and *Functional Progress Form* can be found on pages 102 and 103.

When are reports needed?	Type of Report	Frequency of Report	Billing code	Paid amount	For details see:
When initiating treatment with opioids for chronic, noncancer pain	**Initial report** documenting the need for opioid treatment* (narrative)	All three of these reports are needed at the initiation of treatment for chronic, noncancer pain	1064M	$27.03	WAC 296-20-03020
	Opioid Progress Report Supplement -for baseline measurements of pain/function (department form) *F245-359-000*		1057M	$12.78	WAC 296-20-03021 WAC 296-20-03022 Attached form (page 102)
	Treatment agreement				WAC 296-20-03020 *Sample treatment agreement:* Pages 100-101 of this Provider Bulletin or on the Internet at www.lni.wa.gov/omd/opioids
With ongoing treatment	**Opioid Progress Report Supplement** (department form) *F245-359-000*	At least every 60 days	1057M	$12.78	WAC 296-20-03021 WAC 296-20-03022 Attached form (page 102)
	Functional Progress Form (department form) *F245-363-000*	Use of this form is voluntary but is encouraged after each visit to help track improvement			Attached form (page 103)
	Treatment agreement	Every six months			WAC 296-20-03020 *Sample treatment agreement:* Pages 100-101 of this Provider Bulletin or on the Internet at www.lni.wa.gov/omd/opioids

* No later than thirty days after the attending physician begins treating the worker with opioids for chronic, noncancer pain, the attending physician must submit a written report to the department or self-insurer in order for the department or self-insurer to pay for such treatment. See WAC 296-20-03020 for details.

What are the billing rules?

Physicians should bill the appropriate E&M codes for the evaluation and treatment of injured workers who may require opioids for the treatment of chronic, noncancer pain. Additionally, physicians may bill appropriate local codes, described in the next section, for preparation and submission of the initial documentation which establishes the necessity for treating the worker with opioids (See WAC 296-20-03020) and for the *Opioid Progress Report Supplement* (See WAC 296-20-03021).

What are the billing codes?

Use local code 1064M for the preparation and submission of the initial narrative report establishing the necessity of opioid treatment. This code pays $27.03.

Use local code 1057M for the preparation and submission of the *Opioid Progress Report Supplement.* This code pays $12.78.

Where can I obtain the new opioid forms?

All department forms can be obtained from the warehouse at:

Warehouse
Department of Labor & Industries
PO Box 44843
Olympia, WA 98504-4843

Use form # F245-359-000 to order the required *Opioid Progress Report Supplement*.
Use form # F245-363-000 to order the optional *Functional Progress Form*.

Both of these forms can also be found on the department's Internet home page via the "Forms" link at www.wa.gov/lni

Please note the following regarding coverage for prescriptions of injectable/parenteral opioids.

In general, prescriptions for injectable opioids are not covered. See WAC 296-20-03014 for exceptions. In addition, all other nonoral routes of administration of scheduled drugs that result in systemic availability of the drug equivalent to injectable routes will also not be covered.

For example: Use of the transdermal fentanyl system (Duragesic®) for chronic, noncancer pain will not be routinely covered. We have reviewed the literature and safety profile of this product. While the drug is absorbed relatively slowly, it reaches peak levels equivalent to intravenous use and is metabolized and excreted slowly. Therefore, because the pharmacokinetics of transdermal fentanyl demonstrates systemic availability that is equivalent to injectable routes, this product will not be routinely covered.

In addition, the FDA-approved product labeling states in part that Duragesic® is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain *that cannot be managed by lesser means.*

Therefore, on an exception basis only, the department will pay for the transdermal fentanyl system (Duragesic®) when the patient requires continuous opioid analgesia for pain that cannot be managed by lesser means AND, either

1. Other long-acting opioids cannot be tolerated, or
2. Medical contraindications preclude the use of oral opioids (e.g., the patient can't swallow pills, the patient has dementia and might not take the right amount of pills at the right time.)

Note: This does not apply to the use of opioids in the treatment of cancer pain. See WAC 296-20-03014.

Changes to the Washington Administrative Code (WAC)

Until recently, the Washington Administrative Code (WACs) prohibited payment for opioids prescribed to injured workers for the treatment of chronic pain. Those rules were changed effective January 20, 2000. The revised WACs pertaining to opioids are presented below. (Please see Provider Bulletin 00-01 for a complete listing of the new drug and medication rules.)

WAC 296-20-03014 Which drugs have specific limitations?

(1) **Injectables.** Prescriptions for injectable opioids or other analgesics, sedatives, antihistamines, tranquilizers, psychotropics, vitamins, minerals, food supplements, and hormones are not covered. Exceptions: The department or self-insurer covers injectable medications under the following circumstances.

(a) Indicated injectable drugs for the following:

- Inpatients; or
- During emergency treatment of a life-threatening condition/injury; or
- During outpatient treatment of severe soft tissue injuries, burn or fractures when needed for dressing or cast changes; or
- During the perioperative period and the postoperative period, not to exceed forty-eight hours from the time of discharge.

(b) Prescriptions of injectable insulin, heparin, anti-migraine medications, or impotency treatment, when proper and necessary.

(2) **Noninjectable scheduled drugs administered by other than the oral route.** Nonoral routes of administration of scheduled drugs that result in systemic availability of the drug equivalent to injectable routes will also not be covered.

(3) **Sedative-hypnotics.** During the chronic stage of an industrial injury or occupational disease, payment for scheduled sedatives and hypnotics will not be authorized.

(4) **Benzodiazepines.** Payment for prescriptions for benzodiazepines are limited to the following types of patients:

- Hospitalized patients;
- Claimants with an accepted psychiatric disorder for which benzodiazepines are indicated;
- Claimants with an unrelated psychiatric disorder that is retarding recovery but which the department or self-insurer has temporarily authorized treatment (see WAC 296-20-055) and for which benzodiazepines are indicated; and
- Other outpatients for not more than thirty days for the life of the claim.

(5) **Cancer.** When cancer or any other end-stage disease is an accepted condition, the department or self-insurer may authorize payment for any indicated scheduled drug and by any indicated route of administration.

(6) **Spinal cord injuries.** When a spinal cord injury is an accepted condition, the department or self-insurer may authorize payment for anti-spasticity medication by any indicated route of administration (e.g., some benzodiazepines, Baclofen). Prior authorization is required.

Note: See the department formulary for specific limitations and prior authorization requirements of other drugs.

WAC 296-20-03019 Under what conditions will the department or self-insurer pay for oral opioid treatment for chronic, noncancer pain?

Chronic, noncancer pain may develop after an acute injury episode. It is defined as pain that typically persists beyond two to four months following the injury.
The department or self-insurer may pay for oral opioids for the treatment of chronic, noncancer pain caused by an accepted condition when that treatment is proper and necessary. See WAC 296-20-01002 for the definition of "proper and necessary" health care services.

WAC 296-20-03020 What are the authorization requirements for treatment of chronic, noncancer pain with opioids?

No later than thirty days after the attending physician begins treating the worker with opioids for chronic, noncancer pain, the attending physician must submit a written report to the department or self-insurer in order for the department or self-insurer to pay for such treatment. The written report must include the following:

- A treatment plan with time-limited goals;
- A consideration of relevant prior medical history;
- A summary of conservative care rendered to the worker that focused on reactivation and return to work.
- A statement on why prior or alternative conservative measures may have failed or are not appropriate as sole treatment;
- A summary of any consultations that have been obtained, particularly those that have addressed factors that may be barriers to recovery;
- A statement that the attending physician has conducted appropriate screening for factors that may significantly increase the risk of abuse of adverse outcomes (e.g., a history of alcohol or other substance abuse); and
- An opioid treatment agreement that has been signed by the worker and the attending physician. This agreement must be renewed every six months. The treatment agreement must outline the risks and benefits of opioids use, the conditions under which opioids will be prescribed the physician's need to document overall improvement in pain and function, and the worker's responsibilities.

WAC 296-20-03021 What documentation is required to be submitted for continued coverage of opioids to treat chronic, noncancer pain?

In addition to the general documentation required by the department or self-insurer, the attending physician must submit the following information at least every sixty days when treating with opioids:

- Documentation of drug screenings, consultations, and all other treatment trials;
- Documentation of outcomes and responses, including pain intensity and functional levels; and
- Any modifications to the treatment plan.

The physician must use a form developed by the department, or a substantially equivalent form, to document the patient's improvement in pain intensity and functional levels. This form may be included as part of a sixty-day report.

WAC 296-20-03022 How long will the department or self-insurer continue to pay for opioids to treat chronic, noncancer pain?

The department or self-insurer will continue to pay for treatment with opioids so long as the physician documents:

- Substantial reduction of the patient's pain intensity; and
- Continuing substantial improvement in the patient's function.

Once the worker's condition has reached maximum medical improvement, further treatment with opioids is not payable. Opioid treatment for chronic, noncancer pain past the first three months of such treatment without documentation of substantial improvement is presumed to be not proper and necessary.

WAC 296-20-03023 When may the department or self-insurer deny payment of opioid medications used to treat chronic, noncancer pain?

Payment for opioid medications may be denied in any of the following circumstances:

- Absent or inadequate documentation;
- Noncompliance with the treatment plan;
- Pain and functional status have not substantially improved after three months of opioid treatment; or
- Evidence of misuse or abuse of the opioid medication or other drugs, or noncompliance with the attending physician's request for a drug screen.

WAC 296-20-03024 Will the department or self-insurer pay for nonopioid medications for the treatment of chronic, noncancer pain?

The department or self-insurer may pay for nonopioid medication for the treatment of chronic, noncancer pain when it is proper and necessary.
For example, some drugs such as anti-convulsants, anti-depressants, and others have been demonstrated to be useful in the treatment of chronic pain and may be approved when proper and necessary.